DOCKET

SUPREME COURT
OF THE UNITED STATES

No. 12-142
Title: Mutual Pharmaceutical Company, Inc., Petitioner
v.
Karen L. Bartlett
Docketed: August 1, 2012
Lower Ct: United States Court of Appeals for the First Circuit
Case Nos.: (10-2277)
Decision Date: May 2, 2012

Questions Presented

~~Date~~~	~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~
Jul 31 2012	Petition for a writ of certiorari filed. (Response due August 31, 2012)
Aug 24 2012	Order extending time to file response to petition to and including October 1, 2012.
Aug 31 2012	Brief amicus curiae of Generic Pharmaceutical Association filed.
Aug 31 2012	Brief amici curiae of Morton Grove Pharmaceuticals, Inc., et al. filed.
Sep 27 2012	Order further extending time to file response to petition to and including October 31, 2012.
Oct 31 2012	Brief of respondent Karen L. Bartlett in opposition filed.
Nov 13 2012	DISTRIBUTED for Conference of November 30, 2012.
Nov 13 2012	Reply of petitioner Mutual Pharmaceutical Company, Inc. filed. (Distributed)
Nov 30 2012	Petition GRANTED.
Jan 7 2013	SET FOR ARGUMEMT ON Tuesday, March 19, 2013
Jan 11 2013	Consent to the filing of amicus curiae briefs, in support of either party or of neither party, received from counsel for respondent.
Jan 14 2013	Joint appendix filed (2 volumes). (Statement of costs received.)
Jan 14 2013	Brief of petitioner Mutual Pharmaceutical Company, Inc. filed.
Jan 14 2013	Consent to the filing of amicus curiae briefs in support of either party or neither party received from counsel for the petitioner.
Jan 18 2013	Record received from the U.S.C.A for the First Circuit. (1 Box). Video and Text CD's of the Testimony and Video Deposition are on the P: Drive
Jan 22 2013	Brief amicus curiae of the United States filed.
Jan 22 2013	Brief amicus curiae of Product Liability Advisory Council, Inc. filed.
Jan 22 2013	Brief amici curiae of Chamber of Commerce of the United States of America, et al. filed.
Jan 22 2013	Brief amici curiae of Washington Legal Foundation, and Allied Educational Foundation filed.

Jan 22 2013	Brief amicus curiae of Generic Pharmaceutical Association filed.
Jan 22 2013	Brief amicus curiae of DRI filed.
Jan 22 2013	Brief amici curiae of Ranbaxy Pharmaceuticals Inc., et al. filed.
Jan 28 2013	Record from U.S.D.C.f or the District of New Hampshire is electronic. There are sealed documents in this record.
Jan 28 2013	CIRCULATED.
Feb 13 2013	Brief of respondent Karen L. Bartlett filed. (Distributed)
Feb 20 2013	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
Feb 20 2013	Brief amici curiae of Senator Tom Harkin and Representative Henry A. Waxman filed. (Distributed)
Feb 20 2013	Brief amicus curiae of Council of State Governments filed. (Distributed)
Feb 20 2013	Brief amicus curiae of Dr. John T. Schulz, III filed. (Distributed)
Feb 20 2013	Brief amici curiae of Former FDA Commissioners Dr. Donald Kennedy and Dr. David A. Kessler filed. (Distributed)
Feb 20 2013	Brief amici curiae of John and Tammy Gilbert, et al. filed.
Feb 20 2013	Brief amici curiae of American Association for Justice and Public Justice filed. (Distributed)
Feb 20 2013	Brief amici curiae of Torts Professors filed. (Distributed)
Feb 20 2013	Brief amici curiae of Public Law Scholars filed. (Distributed)
Feb 27 2013	Letter noting amended corporate disclosure statement received from counsel for the petitioner. (DISTRIBUTED)
Mar 4 2013	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED.
Mar 12 2013	Reply of petitioner Mutual Pharmaceutical Company, Inc. filed. (Distributed)
Mar 19 2013	Argued. For petitioner: Jay P. Lefkowitz, New York, N. Y.; and Anthony A. Yang, Assistant to the Solicitor General, Department of Justice, Washington, D. C. (for United States, as amicus curiae.)

PETITION FOR WRIT OF CERTIORARI

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12-142

No.

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the First Circuit erred when it created a circuit split and held—in clear conflict with this Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)—that federal law does not preempt state law design-defect claims targeting generic pharmaceutical products because the conceded conflict between such claims and the federal laws governing generic pharmaceutical design allegedly can be avoided if the makers of generic pharmaceuticals simply stop making their products.

RULE 29.6 DISCLOSURE STATEMENT

Petitioner Mutual Pharmaceutical Company, Inc. ("Mutual") is a wholly owned subsidiary of URL Pharma, Inc., which is a wholly owned subsidiary of Takeda America Holdings, Inc., which is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("Takeda Limited"). Shares of Takeda Limited are traded on the Tokyo Stock Exchange. No other publicly held corporation owns 10 percent or more of Mutual's stock.

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INTRODUCTION

Two terms ago, this Court's decision in *PLIVA, Inc. v. Mensing* foreclosed state-law tort claims targeting generic pharmaceutical products because federal law imposes "an ongoing federal duty of sameness" that precludes generic products from deviating in any material respect from their brand-name equivalents. 131 S. Ct. 2567, 2574-75 (2011) (quotation marks omitted). Since the Court decided that case, the Fifth, Sixth, Eighth, and Ninth Circuits (and literally dozens of state and federal trial courts) have concluded that this Court meant what it said: They categorically have rejected lawsuits targeting generic drug products, including lawsuits that seek to evade *Mensing*'s "sameness" rationale by claiming that generic manufacturers could avoid any conflict between their state tort duties and the federal sameness mandate by simply withdrawing their generic drug products from the market. *See Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011) (vacating its pre-remand opinion despite plaintiff's post-*Mensing* assertion that "there is nothing inconsistent with the Supreme Court decision about holding defendants liable for their failure to suspend sales," *see* Mot. For Leave to File Suppl. Br., *id.*, at *5 (filed Sept. 8, 2011)); *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011) (affirming judgment for generic manufacturers despite plaintiffs' post-*Mensing* claim that the defendants' "decision not to suspend sales and to continue selling their [generic product] is [both] actionable [and] wholly consistent with *Mensing*" because "no federal statute or regulation prohibited them from 'independently' suspending sales of their product," *see* Appellants' Supp. Ltr. Br., *id.*, 2011 WL 3662688,

*5-6 (filed Aug. 15, 2011)); *see also Demahy v. Actavis, Inc.*, 650 F.3d 1045, 1046 (5th Cir. 2011) (remanding case for the entry of judgment in favor of generic manufacturer after *Mensing*); *Gaeta v. Perrigo Pharms. Co.*, 469 Fed. App'x 556 (Feb. 27, 2012) (affirming summary judgment in favor of generic manufacturer after *Mensing*).

The First Circuit's decision in this case openly departs from the holdings of its sister circuits on this issue. And it blasts a gaping hole in *Mensing*, by adopting a rationale that concededly cannot be squared with that decision; that admittedly would have required a different result in that case; and that indeed would sound the death knell for conflict preemption of state-law claims targeting *any* federally regulated product.

In particular, the appellate court narrowly construed *Mensing* as applying only to those claims that are captioned "failure to warn," and therefore declined to apply *Mensing*'s "rationale" to claims that are captioned "design defect," App. 9a-10a—even though it candidly acknowledged that federal law grants generic drug manufacturers no more power to alter the design of their products than it does to alter the labeling of their products, and thus provides no principled basis for distinguishing between failure to warn and design defect claims for purposes of assessing federal law's preemptive effect. App. 10a ("[Petitioner] argues with some force that the generic maker also cannot alter the composition of the drug and so [*Mensing*]'s policy of encouraging generics by preempting state tort claims should extend to design defect as well as claims based on inadequate warning.").

In place of a logical explanation for distinguishing between these claims, the appellate court instead asserted that there is no conflict between state tort law and the federal regulatory regime governing generic drugs because federal law does not obligate generic manufacturers to produce their products in the first place. "[A]lthough Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway), it certainly can choose not to make the drug at all." *Id.* But as the court quickly acknowledged (with some understatement), there is an obvious "tension" between that rationale and *Mensing*, App. 11a, where the generic manufacturers likewise were free "not to make the drug at all." Were the holding below correct, *Mensing* thus would have come out the other way—as the appellate court once again conceded. App. 10a ("[A] generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug.").

As the First Circuit recognized, *Mensing*'s rejection of this radical theory of liability was no oversight. *See id.* ("[T]he FDCA might permit states to tell Mutual it ought not be [making its product] if risk-benefit analysis weights against the drug, *despite what the Supreme Court made of similar arguments in the labeling context.*") (emphasis added). The Eighth Circuit had advanced this very same rationale in its *Mensing* opinion, and this Court both reversed that judgment and then denied a petition for rehearing in which the *Mensing* plaintiffs reiterated the same argument. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label

was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product."); *see also* Resps.' Petition for Reh'g, *Mensing*, 2011 WL 2874547, *1 (filed July 18, 2011) ("Respondents seek rehearing because ... the Petitioner generic drug companies could have 'independently' complied with both state and federal law simply by suspending sales of generic metoclopramide.").

Nor is there is any doubt as to why this Court dismissed that theory. More than twenty years ago, it considered and rejected the so-called "choice of reaction" thesis, which held that federal law does not preempt state tort claims because "compliance with both federal and state law cannot be said to be impossible: [the defendant] can continue to use the [federally approved] label and can at the same time pay damages to successful tort plaintiffs." *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1542 (D.C. Cir. 1984). This Court, however, laid that theory to rest in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992) (plurality opinion) ("[S]tate regulation can be as effectively exerted through an award of damages as through some form of preventive relief.") (quotation marks omitted); *see also id.* at 548-49 (Scalia and Thomas, JJ., concurring in relevant part); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) ("As the plurality opinion said in *Cipollone*, common-law liability is premised on the existence of a legal duty, and a tort judgment therefore establishes that the defendant has violated a state-law obligation. And while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing

conduct and controlling policy.") (quotation marks and citations omitted).

Despite the obvious incompatibility of its rationale with both *Mensing* and these well-settled principles, the First Circuit declared that "it is up to the Supreme Court" to make clear it stands by *Mensing*:

> [H]aving lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief.... [I]t is up to the Supreme Court to decide whether [*Mensing*] is to be enlarged to include design defect claims. Given the widespread use of generic drugs and the developing split in the lower courts ... this issue needs a decisive answer from the only court that can supply it.

App. 11a (internal citations omitted).

With all due respect, that approach is unsustainable. This Court long ago made clear that the lower courts may neither reject rationales that this Court has accepted nor accept rationales that this Court has rejected; indeed, it has summarily reversed decisions that do just that. *See, e.g.*, *Pennsylvania v. Goldhammer*, 474 U.S. 28, 29-30 (1985) (summary reversal warranted because the lower court's "rationale is inconsistent with the rationale of the holding of this Court"); *see also Am. Tradition P'ship, Inc. v. Bullock*, 132 S. Ct. 2490, 2491 (2012) ("[The] arguments in support of the judgment below either were already rejected in

Citizens United, or fail to meaningfully distinguish that case."). To the extent the First Circuit nonetheless has asked this Court to provide "a decisive answer" to its circuit split-creating decision, however, we wholeheartedly agree. This case cries out for review by this Court, and perhaps even for summary reversal.

OPINIONS BELOW

The First Circuit's opinion is reported at 678 F.3d 30, and is reprinted at App. 1-24a. The appellate court's errata to that opinion is reprinted at App. 27-28a. The district court's opinion denying petitioner's renewed motion for judgment as a matter of law is reported at 760 F. Supp. 2d 220, and is reprinted at App. 29-103a. The district court's opinion granting in part and denying in part petitioner's motion for summary judgment is reported at 731 F. Supp. 2d 135, and is reprinted at App. 106-141a. The district court's unpublished order and opinion denying petitioner's motion for judgment on the pleadings is available at 2010 WL 3659789, and is reprinted at App. 142-202a.

JURISDICTION

The First Circuit issued its decision and entered judgment on May 2, 2012, *see* App. 25-26a, and therefore this petition is timely. Petitioners invoke this Court's jurisdiction under 28 U.S.C. § 1254(1).

PERTINENT CONSTITUTIONAL AND STATUTORY PROVISIONS

The Supremacy Clause of the U.S. Constitution provides:

> This Constitution, and the Laws of the United States which shall be made in

> Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. CONST. art. VI, cl. 2.

The pertinent provisions of the federal Food, Drug, and Cosmetics Act are set forth in the Appendix, App. 203-210a.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

In 1984, Congress amended the federal Food, Drug and Cosmetics Act ("FDCA") in order to expand access to affordable generic drugs by reducing barriers to generic market entry. Those amendments—commonly known as the Hatch-Waxman Act—gave birth to the modern generic drug industry, and during the past three decades have reduced pharmaceutical expenditures by trillions of dollars. *Mensing*, 131 S. Ct. at 2582 ("Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public.").

Before Hatch-Waxman, virtually all companies were required to file a New Drug Application ("NDA") to receive Food and Drug Administration ("FDA") approval to market a drug. As part of that process, NDA applicants must conduct extensive and costly clinical trials to prove the safety and efficacy of

a proposed new drug. Hatch-Waxman, however, drew sharp distinctions between branded and generic drug applicants. While brand companies seeking to market an innovative drug product must continue to submit full NDAs (including full clinical trial reports), *see Mensing*, 131 S. Ct. at 2574 (citing 21 U.S.C. § 355(b)(1), (d)), generic drug companies seeking to market copies of previously approved drugs may file an Abbreviated New Drug Application ("ANDA") that simply demonstrates the product's chemical and biological equivalence to a previously approved drug product (known as the "reference listed drug" or "RLD"). *See id.* (citing 21 U.S.C. § 355(j)(2)(A)).

To that end, the statute requires ANDA applicants to show that a generic drug is identical to its brand-name equivalent in all material respects. ANDA applicants therefore must show that the proposed generic drug contains "*the same*" active ingredient(s); employs "*the same*" route of administration (*e.g.*, oral or injected); presents "*the same*" dosage form (*e.g.*, tablet or capsule); and exhibits "*the same*" strength (*e.g.*, 20mg or 40mg) as the branded equivalent, in order to ensure that it will "have *the same* therapeutic effect" as the branded equivalent. 21 U.S.C. § 355(j)(2)(A)(i)-(iv) (emphases added); *Mensing*, 131 S. Ct. at 2574 n.2 (explaining that each generic drug must be "*identical* [to its branded equivalent] in *active ingredients, safety, and efficacy*") (emphasis added). In short, then, the design of a generic drug product must be identical to that of its brand-name counterpart.

As this Court recognized in *Mensing*, it is precisely for that reason that generic product

labeling must at all times be "'the same as the labeling approved for the [brand-name] drug.'" *Mensing*, 131 S. Ct. at 2574 (quoting 21 U.S.C. § 355(j)(2)(A)(v) and citing *id.* § 355(j)(4)(G) (alteration in original)); *see also* FDA, Abbreviated New Drug Application Regulations—Final Rule, 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992) ("[T]he ANDA product's labeling must be the same as the listed drug product's labeling *because* the listed drug product is the basis for ANDA approval.") (emphasis added).

B. The *Mensing* And *Demahy* Cases

Despite the clarity of the statute's sameness requirement, the effect of that rule on state-law tort claims targeting generic pharmaceuticals was unsettled in the lower courts until two terms ago—when this Court decided a pair of cases addressing whether the sameness mandate preempts state tort claims that target generic pharmaceuticals. The first of those cases arose when plaintiff Gladys Mensing filed suit in the U.S. District Court for the District of Minnesota, alleging that she had been injured by long-term consumption of generic metoclopramide (the branded equivalent of which is called Reglan®). Her complaint asserted fourteen different causes of action, including strict liability for both design defect and failure to warn, negligent failure to warn, breach of warranties, misrepresentation, fraud, unfair trade practices, false advertising, and consumer fraud. *See* First Am. Compl., *Mensing v. Wyeth, Inc.*, No. 07-cv-3919 (D. Minn. filed Feb. 22, 2008). The generic manufacturers moved to dismiss her complaint in its entirety as preempted by Hatch-Waxman's sameness mandate, and the district court—treating all her

theories of liability (including design defect) as "essentially 'failure to warn' claims"—ordered an across-the-board dismissal. *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1061 n.6 (D. Minn. 2008).

Mensing appealed, and the Eighth Circuit reversed. 588 F.3d 603. Though it acknowledged that Hatch-Waxman's sameness mandate prohibited the generic defendants from altering their product warnings, it nonetheless held that the generic defendants could have fulfilled their state-law duties without running afoul of that rule. First, it held that they "could have at least *proposed* a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers if approved." *Id.* at 608 (emphasis in original). Second, it held that the generic manufacturers could have fulfilled their state-law duties by "suggest[ing] that the FDA send out a warning letter." *Id.* at 610. Finally, and of special note here, it declared that compliance with state-law tort duties and federal law would not be impossible even if those avenues were *not* available to the generic manufacturers:

> The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales. If Mensing's injuries resulted from their failure to take steps to warn their customers sufficiently of the risks from

> taking their drugs, they may be held liable.

Id. at 611.

While *Mensing* was unfolding in Minnesota, a similar case was proceeding in federal court in Louisiana. As in *Mensing*, plaintiff Julie Demahy alleged that she was injured after taking generic metoclopramide for many years, and her complaint likewise levied an array of state-law claims against the generic product's manufacturer, including failure-to-warn and design-defect claims under the Louisiana Products Liability Act, La. R.S. 9:2800.51 *et seq.*, the Louisiana Unfair Trade Practices and Consumer Protection Law, La. R.S. 51:1401 *et seq.*, and traditional tort theories. *See* Compl., *Demahy v. Wyeth*, No. 2:08-cv-03616-CJB-JCW (E.D. La. filed on removal June 2, 2008).

As in *Mensing*, the generic manufacturer moved to dismiss Demahy's claims on preemption grounds, but the district court denied its motion. The Fifth Circuit then affirmed, echoing the Eighth Circuit's conclusion that the generic defendant could have taken steps to initiate a labeling change by communicating with FDA, and further asserting that Hatch-Waxman's sameness requirement is limited to the period before FDA approval—such that generic companies unilaterally can alter their product labeling after approval through the so-called "Changes Being Effected" or "CBE" process. *Demahy v. Actavis, Inc.*, 593 F.3d 428, 436-46 (5th Cir. 2010).

This Court granted *certiorari* in both cases, and on June 23, 2011 issued a decision reversing both decisions and holding that "federal law preempts these lawsuits." 131 S. Ct. at 2581. The Court's

opinion began by rejecting the Fifth Circuit's assertion that the sameness requirement applies only pre-approval, holding that generic companies cannot utilize the CBE procedure to deviate from the branded product labeling because their labeling must continually be the "same as" the branded product labeling. *Id.* at 2575-76.

It next rejected the plaintiffs' claims that the defendants could have sent "Dear Doctor letters" warning healthcare professionals about the risks of long-term metoclopramide use. The Court observed that such "letters qualify as 'labeling'" subject to the sameness requirement, *id.* at 2576 (citing 21 C.F.R. § 202.1(l)(2) & 21 U.S.C. § 321(m)), and further emphasized that "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Mensing*, 131 S. Ct. at 2576 (citations omitted).

Finally, this Court rejected the appellate courts' assertions that the generic drug manufacturers at least could have "taken steps" to change the product labeling by alerting FDA to the need for stronger warnings. *Id.* at 2579-82. Even though federal law did not prohibit the generic manufacturers from sharing such information with FDA—and indeed, even though the Solicitor General's brief asserted that federal law required the generic defendants to do so—the Court held these claims preempted because FDA still would have had to authorize the use of different product warnings. *Id.* at 2581 ("[W]hen a party cannot satisfy its state duties without the Federal Government's special permission

and assistance ... that party cannot independently satisfy those state duties for pre-emption purposes."). The Court therefore held that the plaintiffs' lawsuits were preempted in their entirety: "[B]ecause pharmacists, acting in full accord with state law, substituted generic metoclopramide [for brand-name Reglan®], federal law pre-empts these lawsuits. We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated." *Id.* (citation omitted).

The plaintiffs in those cases then petitioned this Court for rehearing, emphasizing the Eighth Circuit's pre-*Mensing* assertion that the generic manufacturers could have complied with both the federal sameness mandate and their state-law tort duties *without* requiring FDA's involvement—and thus that their claims were not preempted under *Mensing*'s rationale:

> Petitioners could have satisfied their duty under state tort law by suspending sales of the product with a label that they knew or should have known was inadequate. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009). That course of action was always available to them and could have been accomplished independently, without any action by the FDA. Thus, it was not impossible for the Petitioners to comply with both federal and state law: they 'could independently do under federal law what state law requires of them.

Resps.' Petition for Reh'g, *Mensing*, 2011 WL 2874547, at *2 (parenthetical omitted); *see also id.* at

*1 ("The Court overlooks the fact that the Petitioner[s] could have 'independently' complied with both state and federal law simply by suspending sales of generic metoclopramide with warnings that they knew or should have known were inadequate.").

This Court denied the petition. *Actavis Elizabeth, LLC v. Mensing*, 132 S. Ct. 56 (2011); *PLIVA, Inc. v. Mensing*, 132 S. Ct. 55 (2011). On remand in *Mensing*, the Eighth Circuit explicitly vacated the portion of its earlier opinion holding that the generic manufacturers could be held liable for failing to withdraw their products despite plaintiff's supplemental brief asserting that "nothing in federal law prohibited the Generic Drug Company Appellees from suspending sales of their drug, an action the companies could have taken entirely on their own initiative," Mot. for Leave to File Supp. Br., *Mensing v. Wyeth, Inc.*, No. 08-3850, at 4 (8th Cir. filed Sept. 8, 2012). *See Mensing*, 658 F.3d at 867 ("The Supreme Court having reversed the judgment of this court and remanded this action for further proceedings in light of its opinion in *PLIVA, Inc. v. Mensing*, ... we now vacate Sections I, II, and IV of our opinion in *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009)."). The Fifth Circuit likewise vacated its prior opinion in *Demahy* and ordered the entry of judgment in favor of the generic manufacturer. *See Demahy*, 650 F.3d at 1046.

C. Proceedings Below

On January 8, 2008, Respondent filed suit in New Hampshire state court, alleging that she suffered injuries after ingesting generic sulindac, a non-steroidal anti-inflammatory drug manufactured by

petitioner. App. 1-4a. As in the cases giving rise to *Mensing*, Respondent's complaint raised an array of state-law tort claims—including causes captioned failure-to-warn and design-defect—and Petitioner moved for judgment on the pleadings after removing the case to the U.S. District Court for the District of New Hampshire.

On September 30, 2009, the district court (Laplante, J.) rejected petitioner's federal preemption argument in its entirety, reasoning with respect to respondent's design-defect claim that "[w]hile one way to avoid violating state law in this way would be to redesign Sulindac to remove the alleged defect before distributing the drug (or otherwise to meet the standard of care), another way to do so would be to refrain from distributing it at all." App. 165a. After that decision, all of Respondent's claims were dismissed—either voluntarily or by order of the district court—with the exception of Respondent's state-law design defect claim. App. 4-5a.

That single claim proceeded to trial over a 14-day period in August and September 2010. The jury eventually awarded Respondent over $21 million in damages, App. 5a, and the district court denied Petitioner's post-trial motions (including its renewed preemption defense). App. 29-103a. Petitioner timely appealed to the First Circuit, and on May 2, 2012—despite this Court's decision in *Mensing* and the overwhelming consensus among the lower courts that *Mensing* forecloses these claims—the First Circuit affirmed.

The appellate court began its analysis of the preemption issue by asserting that "[w]hether and to what extent the FDCA preempts design defect claims

against generic drug manufacturers is a question of exceptional importance that the Supreme Court has yet to decide." App. 8a. Yet rather than starting its analysis of that question with *Mensing* (or the dozens of cases that have addressed generic liability after *Mensing*), the appellate court instead turned to this Court's prior decision in *Wyeth v. Levine*, 555 U.S. 555 (2009)—a case that involved *neither* design-defect claims *nor* the federal regulatory scheme governing generic drugs. App. 8-9a. According to the appellate court, however, *Wyeth* established a blanket rule "that state law serves as a 'complementary form of drug regulation,'" App. 9a (quoting *Wyeth*, 555 U.S. at 578), and it asserted without reference to the post-*Mensing* landscape that "[t]he lower courts agree that the FDCA does not preempt state tort suits against drug manufacturers." *Id.*

The appellate court acknowledged that *Wyeth* did not actually address design-defect claims at all, *id.* & n.2 ("*Wyeth*'s holding was technically limited to failure-to-warn claims.") (citing 555 U.S. at 568, 573, 574), but baldly declared that "its logic applies to design defect claims as well." *Id.* (quoting 555 U.S. at 574 for the proposition that "state tort suits 'motivate manufacturers to produce safe and effective drugs *and* to give adequate warnings'") (emphasis in original).

In contrast to this "general no-preemption rule," App. 11a, the First Circuit claimed that *Mensing* merely "carved out an exception to *Wyeth*, finding that the FDCA preempts *failure-to-warn* claims against *generic* drug manufacturers ... [because] the generic maker cannot alter the labeling." App. 9-10a

(emphases in original); App. 10a ("[T]he Supreme Court [has] not yet said it would extend [*Mensing*]'s exception to design defect claims."). But the court did not explain how the design-defect claim at issue here can be distinguished from the failure-to-warn claims it said were at issue in *Mensing*. App. 7a (conceding that New Hampshire has adopted *Restatement (Second) Torts* § 402A, cmt. k, such that design-defect liability hinges on the absence of an adequate warning). And it acknowledged that targeting the product's design instead of its label did not in any event provide a conceptually coherent basis for distinguishing *Mensing*: Just as *Mensing* held that federal law precludes manufacturers from altering generic product labeling, the appellate court expressly conceded that under federal law "Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)." App. 10a.

The court nonetheless concluded that generic drug manufacturers like Petitioner can escape the clear conflict between their state-law duties and federal sameness obligations by "choos[ing] not to make the drug at all; and the FDCA might permit states to tell Mutual it out not be doing so if risk-benefit analysis weighs against the drug." *Id.* Yet it once again conceded that this rationale likewise was impossible to square with *Mensing*, where the very same arguments had been made and rejected. App. 11a (admitting that this claim is "in tension" with "*[Mensing]*'s rationale" because "a generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug"); App. 10a-11a (suggesting that "the Supreme Court might be less ready to deprive Bartlett of her remaining

avenue of relief ... *despite what the Supreme Court made of similar arguments in the labeling context.*") (emphasis added).

Faced with a choice between what it called the "logic" of *Wyeth* and the "rationale" of *Mensing*, the court ultimately punted the issue to this Court—declaring that it would allow the jury's verdict to stand unless and until this Court instructs otherwise:

> [I]t is up to the Supreme Court to decide whether *PLIVA*'s exception is to be enlarged to include design defect claims. Given the widespread use of generic drugs and the developing split in the lower courts, this issue needs a decisive answer from the only court that can supply it.

App. 11a (internal citations and reference omitted). This petition follows.

REASONS FOR GRANTING THE WRIT

The First Circuit plainly erred when it created a circuit split by holding that federal law does not preempt state law design-defect claims targeting generic pharmaceutical products on the ground that the conceded conflict between such claims and the federal laws governing generic pharmaceutical design allegedly can be avoided if the makers of generic pharmaceuticals simply stop making their products. Given the lopsided split created by the appellate court's decision; the appellate court's admission that its reasoning cannot be squared with *Mensing*; the fact that its approach to preemption otherwise has been rejected by this Court for more

than twenty years; and the court's own request for "a decisive answer from [this] court," this Court should grant the writ and reverse the decision, perhaps even summarily.

A. The First Circuit's Opinion Cannot Be Squared With *Mensing*, As Every Other Appellate Court Has Recognized And The First Circuit Itself Conceded.

Since this Court decided *Mensing*, every other appellate court that has considered whether state law design-defect claims survive that decision has found them to be preempted. *Gaeta*, 469 Fed. App'x 556; *Mensing*, 658 F.3d 867; *Smith*, 657 F.3d 420; *Demahy*, 650 F.3d 1045. So have scores of state and federal district courts, which uniformly have rejected the First Circuit's remarkable claim that generic manufacturers can be held liable under state law for declining to pull their federally approved products off the shelf. *See, e.g.*, *Aucoin v. Amneal Pharm., LLC*, 2012 WL 2990697, at *10 (E.D. La. July 20, 2012); *Johnson v. Teva Pharm. USA, Inc.*, 2012 WL 1866839, at *4 (W.D. La. May 21, 2012); *Eckhardt v. Qualitest Pharm. Inc.*, 2012 WL 1511817, at *7 (S.D. Tex. Apr. 30, 2012); *Lyman v. Pfizer, Inc.*, 2012 WL 368675, at *4 (D. Vt. Feb. 3, 2012); *In re Darvocet*, 2012 WL 718618, at *3 (E.D. Ky. Mar. 5, 2012); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, __, 2012 WL 272889, at *3 (E.D.N.Y. Jan. 30, 2012); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 662 (D. Md. 2011); *In re Fosamax*, 2011 WL 5903623, at *6 & n.5 (D.N.J. Nov. 21, 2011); *Stevens v. PLIVA, Inc.*, 2011 WL 6224569, at *2 (W.D. La. Nov. 15, 2011).

This overwhelming nationwide consensus is not surprising. Before *Mensing* reached this Court, the

Eighth Circuit had advanced the very same theory embraced by the First Circuit's decision here. It held:

> The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product. Instead, they are alleged to have placed a drug with inadequate labeling on the market and profited from its sales. If Mensing's injuries resulted from their failure to take steps to warn their customers sufficiently of the risks from taking their drugs, they may be held liable.

Mensing, 588 F.3d at 611.

Needless to say, this Court *reversed* that judgment, albeit without specifically referencing the Eighth Circuit's "they could have stopped selling the product" argument. And it again rejected the argument when the *Mensing* plaintiffs attempted to revive it in a post-decision petition for rehearing, Resps' Petition for Reh'g, *Mensing*, 2011 WL 2874547, at *1 ("Respondents seek rehearing because ... the Petitioner generic drug companies could have 'independently' complied with both state and federal law simply by suspending sales of generic metoclopramide."). *See* 132 S. Ct. 55 (denying petition for reh'g); 132 S. Ct. 56 (same).

Since that time, every other appellate court has (and scores of trial courts have) followed this Court's lead in rejecting the Eighth Circuit's pre-*Mensing*

rationale for imposing liability on generic product manufacturers. *See, e.g.*, *In re Darvocet*, 2012 WL 718618, at *3 (highlighting the rejection of this claim in *Mensing* and the fact that Sixth and Eighth Circuits rejected it after it was raised by plaintiffs in post-*Mensing* briefs); *Gross*, 825 F. Supp. 2d at 662 (same); *Fullington v. PLIVA, Inc.*, 2011 WL 6153608, at *6 (E.D. Ark. Dec. 12, 2011) ("[Plaintiff] contends that ... the generic manufacturers could have complied with both state and federal law by simply pulling the drug off the market entirely. While the Eighth Circuit in *Mensing* agreed with this argument, the Supreme Court reversed the Eighth Circuit's judgment in *Mensing*. The Eighth Circuit then vacated the portions of its *Mensing* opinion that addressed preemption, including the section adopting the argument that impossibility preemption did not apply because the manufacturers could pull the drug from the market.") (citation omitted).

The First Circuit, by contrast, deemed *Mensing* to be a narrow and essentially unprincipled exemption from what it called *Wyeth*'s "general no-preemption rule" for state tort claims under the FDCA, App. 11a—characterizing *Mensing* as a narrow "exception to *Wyeth*, finding [only] that the FDCA preempts *failure-to-warn* claims against *generic* drug manufacturers." App. 9-10a (emphases in original); *see also* App. 10a ("[T]he Supreme Court [has] not yet said it would extend *PLIVA*'s exception to design defect claims.").

That assertion fundamentally misconstrues both *Wyeth* and *Mensing*. *Mensing* was not an arbitrary and unprincipled "exception" to *Wyeth*. As *Mensing* instead took pains to explain, both decisions reflect a

single, entirely coherent principle: that drug manufacturers may be held liable under state law if and only if the federal laws governing their drug products authorize them to change the allegedly offensive elements of those products without prior FDA approval. It is that consistent principle that led the Court to allow failure-to-warn claims against brand manufacturers but reject them against generic manufacturers. *See Mensing*, 131 S. Ct. at 2582 ("It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme.").

The appellate court thus fundamentally erred in asserting that *Wyeth* somehow established a "general no-preemption rule" with respect to state tort claims implicating the FDCA. Instead, as the First Circuit's decision elsewhere recognized, *Wyeth* reasoned only that federal law does not preempt state law failure-to-warn claims against brand manufacturers *because federal law expressly empowers such companies to unilaterally alter the warnings in their product labeling*. *See* App. 9a n.2 ("Because the FDA's 'changes being effected' regulations ... permit brand-name manufacturers to strengthen their labels unilaterally ... [*Wyeth*] concluded it is possible for brand-name manufacturers to comply with both

federal labeling requirements and state tort law effectively requiring a stronger label.") (internal citation omitted; discussing *Wyeth*, 555 U.S. at 568, 573).

The opposite is true of generic manufacturers. Hatch-Waxman's "sameness" mandate expressly precludes them from unilaterally altering either the label or design of their generic drug products. *Mensing*, 131 S. Ct. at 2574 & n.2 (explaining that the statute requires each generic drug to be "identical [to its branded equivalent] in active ingredients, safety, and efficacy" as well as in "the safety and efficacy labeling") (quotations and original alterations omitted). As a result, *Mensing* is not an exception to *Wyeth*; these two cases stand for the very same principle, and the First Circuit was dead wrong in suggesting that *Wyeth* somehow established a blanket "no-preemption rule" whose "logic" should apply here. App. 9a, 11a.

The appellate court nonetheless asserted that *Mensing* might be limited to claims that are captioned "failure to warn" as opposed to "design defect." App. 10a ("[T]he Supreme Court [has] not yet said it would extend [*Mensing*]'s exception to design defect claims."). But the court offered no rationale for distinguishing between failure-to-warn and design-defect claims. And there is none. In the prescription-drug context, failure-to-warn and design-defect claims are one and the same: even the First Circuit conceded that under *comment k*,[1]

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[1] *Restatement (Second) of Torts* § 402A comment k (1965) ("There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their

design-defect liability is predicated on the absence of an adequate warning. App. 7a ("[A]n ordinary consumer would hardly know *without further warning* that sulindac or any other ordinary analgesic carries a risk of the kind of ill effects and suffering that Bartlett encountered.") (emphasis added); *id.* ("Mutual could still have avoided liability by proving that sulindac was unavoidably unsafe but was highly useful *and had an adequate safety warning.*") (emphasis added; citing *Restatement (Second) Torts* § 402A cmt. k and the district court's analysis of *comment k*, App. 125a-128a (denying Mutual's motion for summary judgment because "the adequacy of Sulindac's safety warning is a matter of genuine dispute on this record" and because the adequacy of the warning is "a trialworthy issue")). These bedrock tort principles, of course, explain why the district court in *Mensing* treated all of Ms. Mensing's claims as "essentially failure-to-warn claims" for preemption purposes, including her strict-liability design-defect claim. *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1061 n.6 (D. Minn. 2008). And it likewise is why this Court later held in *Mensing*

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intended and ordinary use. These are especially common in the field of drugs.... Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.... The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use.").

that "federal law pre-empts *these lawsuits*." 131 S. Ct. at 2581 (emphasis added).

But even if there were some daylight between "failure to warn" and "design defect" claims—and again, the First Circuit failed to identify any—there still would be no basis for distinguishing between them for Hatch-Waxman preemption purposes. As the First Circuit once again conceded, federal law gives generic manufacturers no more power to alter a generic product's design than it does to alter its labeling: Given Hatch-Waxman's sameness mandate, generic companies like "[Petitioner] cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)." App. 10a.

Because the same "sameness" principle on which *Mensing* turned thus applies equally to claims labeled both "failure to warn" and "design defect," countless courts (as the First Circuit openly acknowledged) have rejected the appellate court's unprincipled attempt to distinguish between such claims for post-*Mensing* preemption purposes. App. at 10-11a & n.3 (identifying the "developing split in the lower courts," which the First Circuit itself created); *see also Aucoin*, 2012 WL 2990697, at *9 ("Defendant could not alter the design of the drug without violating federal law and this duty of sameness, making it impossible for Defendant independently to comply with both federal and state law. As such, this Court joins numerous other lower courts that have considered this issue and found the failure-to-warn reasoning of *Mensing* equally applicable to a design defect claim."); *Johnson*, 2012 WL 1866839, at *4 ("The FDCA likewise prevented

the Generic Defendants from altering unilaterally the design of the drug itself.... Accordingly, [plaintiff] cannot show that an alternative drug design was available to the Generic Defendants, and her design defect claims will be dismissed as preempted"); *Eckhardt*, 2012 WL 1511817, at *7 ("Generics were required to produce a drug that was equivalent to the brand-name drug and were not free to unilaterally pursue a safer alternative design in order to comply with state law. The design defect claim is thus preempted and therefore dismissed."); *Lyman*, 2012 WL 368675, *4 ("The Generic Defendants' 'federal duty of sameness' ... applies to the design or composition of the drug as well as to its labeling. Applying the *Mensing* holding requires dismissal of the Lymans' design claims as well.") (citation omitted; quoting *Mensing*, 131 S. Ct. at 2575); *In re Darvocet*, 2012 WL 718618, *3 (rejecting design defect claims because "the Generic Defendants, bound by their 'ongoing federal duty of sameness,' were powerless to change" the product's design) (quoting *Mensing*, 131 S. Ct. at 2575); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d at __, 2012 WL 272889, at *3 ("[T]he federal duty of sameness also applies in the context of generic drug design, and federal law preempts state laws imposing a duty to change a drug's design on generic drug manufacturers") (citation and quotation marks omitted); *In re Fosamax*, 2011 WL 5903623, at *6 ("[I]t was not lawful under federal law for the [generic manufacturers] to do what state law required of them because FDA requires [the] generic [product] to have the same active ingredient as" its branded equivalent) (citation and quotation marks omitted); *Stevens*, 2011 WL 6224569, at *2 ("Under

the same federal law analyzed in *Mensing*, a generic pharmaceutical product must be the same as [its branded equivalent] in active ingredients, safety and efficacy and hence, as was the case with labeling, federal law pre-empts state laws imposing the duty to change a drug's design.") (citation omitted).

B. The First Circuit's Stop-Manufacturing Theory Only Exacerbates The Conflict Between Its Decision And This Court's Precedents.

The First Circuit nonetheless sought to evade this obvious conflict between the federal sameness mandate and state law design-defect claims by asserting that Petitioner could simply stop making its generic product—and thereby could comply simultaneously with both its federal obligations and state tort-law duties. App. 10a ("[A]lthough [Petitioner] cannot legally make sulindac in another composition ... it certainly can choose not to make the drug at all."). Rather than solving the conflict between the appellate court's decision and this Court's precedents, however, that line of reasoning only exacerbates it.

As the First Circuit again acknowledged, this very same end-run around federal law's preemptive effect was attempted and rejected in *Mensing*: "[A] generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug," yet *Mensing* nonetheless foreclosed any claim challenging generic product warnings. App. 11a; *see also* App. 10a ("[A generic drug manufacturer] can choose not to make the drug at all; and the FDCA might permit states to tell [the company that] it ought not be doing so if risk-benefit analysis weighs

against the drug, *despite what the Supreme Court made of similar arguments in the labeling context.*") (emphasis added).

There is no doubt why that theory was rejected: Accepting it would "render conflict pre-emption largely meaningless because it would make most conflicts between state and federal law illusory." *Mensing*, 131 S. Ct. at 2579. After all, the same argument "could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether." *In re Darvocet*, 2012 WL 718618, at *3 (citing *Mensing*, 131 S. Ct. at 2579); *see also In re Fosamax*, 2011 WL 5903623, at *6 n.5 ("Plaintiffs insist that Generic Defendants could have simply removed alendronate sodium from the market. Whatever the merit of that contention, it is essentially a re-argument of *Mensing*.").

Indeed, the conflict between this line of reasoning and this Court's prior precedents is not limited to *Mensing*; it flies in the face of nearly two decades of decisions rejecting the so-called "choice of reaction" theory pioneered by the D.C. Circuit's 1984 decision in *Ferebee v. Chevron Chemical Co.* That case famously rejected a federal preemption defense based on EPA's approval of pesticide product labeling under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), on the ground that "compliance with both federal and state law cannot be said to be impossible: [the defendant] can continue to use the EPA-approved label and can at the same time pay damages to successful tort plaintiffs." 736 F.2d at 1542. The "choice" of what to do, *Ferebee* asserted, was the defendant's: Faced with a possible

award of damages under state law, the defendant could either "choose" to keep its label and pay out tort verdicts, or else "choose not to send [its product] into Maryland." *Id.* at 1543.

Suffice it to say, *Ferebee*'s assertion that this "choice" sufficed to evade federal law's preemptive effect was widely panned in the lower courts—including by the First Circuit, which explained that the supposed "choice" of paying monetary damages or altering one's course of conduct is "akin to the free choice of coming up for air after being underwater." *Palmer v. Liggett Grp., Inc.*, 825 F.2d 620, 627 (1st Cir. 1987); *see also MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994) ("[T]his argument is sophistry. If plaintiffs could recover large damage awards because the herbicide was improperly labeled under state law, the undeniable practical effect would be that state law *requires* additional labeling standards not mandated by FIFRA; it cannot be presumed that businesses wish to bring about their own economic suicide.") (emphasis in original); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370 (7th Cir. 1993) ("[D]amages actions, just like regulatory mandates, cause companies to modify their economic decisions. It would be silly to pretend that federal lawmakers, seeking to occupy a whole field of regulation, wouldn't also be concerned about the distorting effects of tort actions."); *Worm v. Am. Cyanamid Co.*, 970 F.2d 1301, 1307 (4th Cir. 1992) ("We find the distinction illusory. ... Implicit in the Worms' argument is a notion that common law tort duties are not regulatory. But surely a jury verdict resulting from a pesticide manufacturer's failure to warn of the dangers of the product has an effect no different from a legislatively enacted state regulation

requiring the insertion of a specific warning on the pesticide label.").

The issue eventually reached this Court in *Cipollone*, and this Court decisively rejected *Ferebee*'s claim that state-law damage awards do not constitute state regulatory "requirements" that conflict with federal law:

> As we noted in another context, 'state regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'

Cipollone, 505 U.S. at 521 (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) ("As the plurality opinion said in *Cipollone*, common-law liability is premised on the existence of a legal duty, and a tort judgment therefore establishes that the defendant has violated a state-law obligation. And while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy.") (internal quotation marks and citation omitted).

As these cases make clear, this Court long ago recognized that requiring manufacturers of federally regulated products to withdraw their products from the market or else face state-law damage awards does not *avoid* the conflict between federal law and state tort-law obligations. It *exacerbates* that conflict and effectively inverts the Supremacy Clause, by

ensuring that the state law requirements come out on top every time. Indeed, the First Circuit's attempt to revive this long-discredited approach would toll the bell for conflict preemption of state tort claims involving *any* federally regulated product, since no federal statute that we can identify compels manufacturers to market their products in interstate commerce (and since this Court's recent decision in *The Healthcare Cases*, 132 S. Ct. 2566 (2012), would cast grave doubt on the constitutionality of such a requirement in any event). In short, because the manufacturer of *any* product can in theory "choose" to stop selling that product in any given State, no federal requirement ever could generate a preemptive conflict under the First Circuit's radical approach.

Allowing the First Circuit's decision to stand would be particularly pernicious in this context, and it is hard to imagine a result more at odds with this federal scheme. Hatch-Waxman's whole aim, after all, was to make generic copies of approved brand-name drugs widely available to the public and thereby lower healthcare costs; as *Mensing* itself observed, "it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public." 131 S. Ct. at 2582. The First Circuit acknowledged as much: "There is no doubt that Congress wanted to reduce medical costs by spurring generic copycat drugs [and *Mensing*] held that Congress cannot have wanted the generic to pay damages under state law for a label that the FDA required." App. 10a. But the appellate court simply didn't care—casually asserting that it would refuse to apply *Mensing* to any claim not captioned

"failure to warn" unless and until this Court made clear that it meant what it said. App. 11a ("Bartlett having lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief."); *id.* ("[I]t is up to the Supreme Court to decide whether [*Mensing*]'s exception is to be enlarged to include design defect claims. Given the widespread use of generic drugs and the developing split in the lower courts, this issue needs a decisive answer from the only court that can supply it.") (internal citations omitted).

C. This Court Should Consider Summary Reversal.

The First Circuit's rejection of this Court's precedents is so transparent that the Court should consider summary reversal. The panel recognized that there is no logical difference between design-defect and failure-to-warn claims for purposes of assessing preemption under the Hatch-Waxman Act. App. 10a ("Mutual argues with some force that the generic maker also cannot alter the composition of the drug and so [*Mensing*]'s policy of encouraging generics by preempting state tort claims should extend to design defect as well as claims based on inadequate warning."). The panel acknowledged that this Court considered and rejected the very same theory of liability when it reviewed the Eighth Circuit's decision in *Mensing*. *Id.* ("[T]he FDCA might permit states to tell Mutual it ought not be [selling its product] *despite what the Supreme Court made of similar arguments in the labeling context.*") (emphasis added). And the panel conceded that the

"rationale" of *Mensing* applies no less here than it did there. App. 11a.

Even so, the panel declined to follow the logic of this Court's decisions, choosing instead to adopt a rationale that it admitted would have produced the opposite outcome in *Mensing*. *Id.* ("[A] generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug."). And the panel effectively dared this Court to say that *Mensing* meant what it said. "Bartlett having lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief." *Id.* Yet as *Mensing* explained, it was not "mere chance" that Ms. Bartlett's pharmacist supplied a generic; that was the anticipated and intended consequence of the Hatch-Waxman Act, which lowers the cost of health care for all of us. 131 S. Ct. at 2581. And she did not "lose" her warning claim; the "special, and different, regulation of generic drugs" under federal law meant that the Constitution bars states from imposing liability on a manufacturer that has no ability to change its product. *Id.*

Perhaps, to use *Mensing*'s words, "from the perspective of [the First Circuit], finding pre-emption here but not in *Wyeth* makes little sense." *Id.* But in our hierarchical system, lower courts may not decline to apply this Court's rationales to materially indistinguishable cases merely because of policy disagreement—and this Court likewise has made clear that summary reversal is appropriate where the lower courts adopt a rationale that this Court has rejected. *See, e.g.*, *Goldhammer*, 474 U.S. at 29-

30 (summary reversal warranted because the lower court's "rationale is inconsistent with the rationale of the holding of this Court."); *see also Am. Tradition P'ship, Inc.*, 132 S. Ct. at 2491.

Given the First Circuit's own request for "a decisive answer" to its circuit split-creating decision, App. 11a, however, we respectfully submit that this Court should supply it. The petition should be granted, and the Court should consider summarily reversing the appellate court's decision.

CONCLUSION

For the foregoing reasons, the petition should be granted and the appellate court's judgment reversed.

July 31, 2012

Respectfully submitted,

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APPENDIX

United States Court of Appeals
For the First Circuit

No. 10-2277

KAREN L. BARTLETT,

Plaintiff, Appellee,

GREGORY S. BARTLETT,

Plaintiff,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,

Defendant, Appellant,

UNITED RESEARCH LABORATORIES, INC., n/k/a URL Pharma, Inc.; BROOKS PHARMACY,

Defendants.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW HAMPSHIRE

[Hon. Joseph N. Laplante, U.S. District Judge]

Before

Boudin, Stahl and Thompson,

Circuit Judges.

Joseph P. Thomas with whom Linda E. Maichl, Paul J. Cosgrove, Ulmer & Berne LLP, Stephen J. Judge, Pierre A. Chabot and Wadleigh, Starr & Peters PLLC were on brief for appellant.

Joseph P. Lucia, David R. Geiger, Nabeel Ahmad, Foley Hoag LLP and Hugh F. Young, Jr., Product Liability Advisory Council, Inc., on brief for the Product Liability Advisory Council, Inc., Amicus Curiae.

Keith M. Jensen with whom Eric N. Roberson, Jensen & Associates, PLLC, Steven M. Gordon, Christine M. Craig and Shaheen & Gordon were on brief for appellee.

Louis M. Bograd, Center for Constitutional Litigation, P.C., Andru H. Volinsky, Chair, New Hampshire Association for Justice Amicus Committee, and Bernstein Shur, P.C. on brief for the American Association for Justice and the New Hampshire Association for Justice, Amici Curiae.

May 2, 2012

BOUDIN, Circuit Judge. This products liability case arises out of severe and permanent injuries sustained by plaintiff Karen Bartlett after taking sulindac, a generic non-steroidal anti-inflammatory drug ("NSAID") manufactured by (among others) defendant Mutual Pharmaceutical Company ("Mutual"). Sulindac is known to cause, in rare instances, a hypersensitivity reaction called Stevens-Johnson Syndrome and its more generous cousin toxic epidermal necrolysis ("SJS/TEN"). In December 2004, Bartlett's doctor prescribed (for her shoulder pain) sulindac under the brand-name Clinoril made by the original provider, and her pharmacist dispensed generic sulindac.

The consequences were disastrous. Bartlett developed SJS/TEN early in 2005. TEN is diagnosed when 30 percent or more of the outer skin layer on a patient's total body surface area has deteriorated, been burned off or turned into an open wound. In Bartlett's case, the percentage rose to 60-65 percent of her body; she spent 70 days at Massachusetts General Hospital--including over 50 in its burn unit. Both her suffering and permanent injury, including permanent near-blindness, are described below in connection with the award of damages.

Bartlett brought a bevy of claims against Mutual in New Hampshire state court, including claims for breach of warranty, fraud, and negligence, as well as the perennial trio of products liability claims: design defect, failure to warn, and manufacturing defect. After Mutual removed the case to federal court on diversity grounds, all but the design defect claim were dismissed by the district court on summary judgment or voluntarily by Bartlett. Bartlett v. Mutual Pharm.

Co., No. 08–cv–358, 2010 WL 3659789 (D.N.H. Sept. 14, 2010); Bartlett v. Mutual Pharm. Co., 731 F. Supp. 2d 135 (D.N.H. 2010).

Bartlett originally planned her evidence across a range of possible claims, including an attack on the adequacy of the warning label and information that accompanied Mutual's sulindac drug. It was not until after the trial was completed that further legal developments (discussed below) foreclosed a direct attack on the adequacy of the label; but the district court dismissed Bartlett's warning claim because her prescribing doctor admitted that he had not read the box label or insert. Bartlett, 731 F. Supp. 2d at 146-49.

Although Bartlett's experts had prepared their initial reports to cover multiple theories advanced in the complaint, by trial the core remaining theory of design defect was narrowed to this: that sulindac's risks outweighed its benefits making it unreasonably dangerous to consumers, despite the federal Food and Drug Administration ("FDA") having never withdrawn its statutory "safe and effective" designation that the original manufacturer had secured and on which Mutual was entitled to piggyback. See 21 U.S.C. §§ 355(b)(1), (d) (2006); id. § 355(j)(2)(A).

A 14-day trial occurred in late August and early September 2009, during which Bartlett called witnesses to her suffering and her treatment, including two important experts: a burn surgeon and--more critical to design defect--a pharmacologist/ toxicologist. The latter expert in particular sought to show from incident reports made to the FDA and other information that sulindac had a worse record of causing SJS/TEN than other available drugs, and a

safety profile similar to other drugs deemed dangerous enough to have been withdrawn from the market--such as valdecoxib, another NSAID sold under the brand name Bextra, which was withdrawn in 2005.

Mutual had designated its own expert in the same field as well as other witnesses but ultimately chose to put on no affirmative case of its own, although it cross-examined Bartlett's experts vigorously and offered substantial legal arguments to the judge as to why it should not be found liable. After several days of deliberation, the jury found for Bartlett and awarded $21.06 million in compensatory damages. The district court denied Mutual's motion for judgment as a matter of law, Fed. R. Civ. P. 50(b), and motion for a new trial, Fed. R. Civ. P. 59. Bartlett v. Mutual Pharm. Co., 760 F. Supp. 2d 220 (D.N.H. 2011).

Mutual now appeals, arguing that the district court misunderstood New Hampshire law on design defect claims; that such claims as to generic drugs are preempted under federal law; that causation was not proved; that Bartlett's expert evidence was inadmissible on multiple grounds; that instructions as to label warnings were inaccurate; that misconduct by Bartlett's counsel required a new trial; and that damages were excessive and required a new trial. The standard of review depends upon the issue, the first two raising strictly issues of law that we review de novo. U.S. ex rel. Loughren v. Unum Grp., 613 F.3d 300, 307-08 (1st Cir. 2010).

Design Defect. Although courts "traditionally have refused to review the reasonableness of the designs of prescription drugs," Restatement (Third) of Torts: Products Liability § 6, cmt. f, at 156 (1998), this court reads New Hampshire law now to permit such review,

Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 655 (1st Cir. 1981). Brochu is consistent with the New Hampshire Supreme Court's adoption of Restatement (Second) of Torts § 402A (1965), see Buttrick v. Lessard, 260 A.2d 111, 113 (N.H. 1969), which "imposes liability for selling 'any product in a defective condition unreasonably dangerous to the user or consumer' when the product causes injury to the user or consumer."

However, Mutual interprets Buckingham v. R.J. Reynolds Tobacco Co., 713 A.2d 381 (N.H. 1998), to require not merely unreasonable dangerousness but also proof that there exists an alternative, safer design for the product (like a new guard on a motorized table saw), see id. at 384. The claim in Brochu could satisfy such a test, because the drug at issue there contained a mix of progestogen and estrogen, and its unreasonable dangerousness could be attributed to the design-flaw of an unnecessarily high proportion of estrogen.

By contrast, Mutual says that Bartlett failed to allege and prove that sulindac could be made in a different and safer form, and this almost certainly has to be true: sulindac is a one-molecule drug; and the variations in suldinac as sold consist of inactive ingredients that ordinarily do not have significant pharmacological effects. But Buckingham does not clearly say that a safer alternative is a necessary element of design defect over and above an unreasonably dangerous product, and a subsequent decision disavows any such requirement.

In Vautour v. Body Masters Sports Indus., Inc., 784 A.2d 1178, 1183 (N.H. 2001), which followed after Buckingham, the New Hampshire Supreme Court held that proof of a safer alternative design "should be

neither a controlling factor nor an essential element that must be proved in every [design defect] case." Rather, it said that "a product is defective as designed 'if the magnitude of the danger outweighs the utility of the product.'" Id. at 1182 (quoting Keeton et al., Prosser and Keeton on the Law of Torts § 99, at 699 (5th ed. 1984)).

Buckingham involved a design defect claim against cigarette manufacturers, and the court dismissed the claim on the ground that cigarettes are inherently dangerous and commonly known to be so. 713 A.2d at 384; see also Restatement (Second) of Torts § 402A, cmt. i (danger "beyond that which would be contemplated by the ordinary consumer"). But an ordinary consumer would hardly know without further warning that sulindac or any other ordinary analgesic carries a risk of the kind of ill effects and suffering that Bartlett encountered.

Accordingly, the district court properly allowed Bartlett to show that sulindac was in a "defective condition" by showing that it was "unreasonably dangerous" due to its propensity to cause SJS/TEN--a harrowing hypersensitivity reaction characterized by necrosis of the skin and mucous membranes, and often causing blindness or death. Although Mutual could still have avoided liability by proving that sulindac was unavoidably unsafe but was highly useful and had an adequate safety warning, Bartlett, 731 F. Supp. 2d at 150-51; Restatement (Second) Torts § 402A, cmt. k, Mutual abandoned that defense on the eve of trial.[1]

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[1] Although Mutual has not explained its strategy, the district court had already rejected Bartlett's claims based on failure to warn for lack of causation, and Mutual may have hoped to exclude entirely any evidence of the warnings actually employed by Mutual, which

Mutual restates its no-defect argument as an issue of causation; but given the overwhelming evidence that sulindac triggered Bartlett's reaction, "but for" cause is plainly established, Bartlett, 760 F. Supp. 2d at 246. Mutual's position that "Bartlett could not present evidence that a non-existent defect in the sulindac proximately caused her injury," merely restates the argument about New Hampshire law that we have just rejected.

Preemption. The most far-reaching of Mutual's objections is that Bartlett's design defect claim is preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), and--in particular--by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355(j)(2)(A)) ("Hatch-Waxman Amendments"), and its regulations. Whether and to what extent the FDCA preempts design defect claims against generic drug manufacturers is a question of exceptional importance that the Supreme Court has yet to decide.

Because prescription drugs and their warnings are closely regulated by the FDA, Congress might explicitly, or the Supreme Court by implication, have preempted state design defect or inadequate warning claims that allow state juries to second-guess the FDA's seal of approval. But the statute contains no general preemption provision, and in Wyeth v. Levine,

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had listed SJS/TEN as a potential "adverse reaction" in its package insert without explicitly naming SJS/TEN on the label's "warnings" section. Or, it may have thought that Bartlett's expert testimony could be undermined without risking cross-examination of its own expert who might have had to concede some of the dangers posited by Bartlett.

555 U.S. 555 (2009), the Supreme Court rejected implied preemption, saying that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," id. at 575, and that state law serves as a "complementary form of drug regulation," id. at 578.

Although Wyeth's holding was technically limited to failure-to-warn claims,[2] its logic applies to design defect claims as well. See Wyeth, 555 U.S. at 574 (state tort suits "motivat[e] manufacturers to produce safe and effective drugs and to give adequate warnings") (emphasis added); cf. Wimbush v. Wyeth, 619 F.3d 632, 645 & n.7 (6th Cir. 2010) (negligent marketing claim not preempted). The lower courts agree that the FDCA does not preempt state tort suits against drug manufacturers. See Riegel v. Medtronic, Inc., 552 U.S. 312, 340 n.11, 343 n.16 (2008) (Ginsburg, J., dissenting) (collecting cases).

However, in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), the Court carved out an exception to Wyeth, finding that the FDCA preempts failure-to-warn claims against generic drug manufacturers. Generic drug manufacturers, unlike brand-name manufacturers, cannot unilaterally change their labels, 21 C.F.R. § 314.94(a)(8)(iv) (2011), and thus cannot

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[2] More specifically, Wyeth held that the FDCA does not preempt failure-to-warn claims against brand-name drug manufacturers. Because the FDA's "changes being effected" regulations, 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2008), permit brand-name manufacturers to strengthen their labels unilaterally--albeit temporarily, while application for permanent change is pending with the FDA--the Court concluded it is possible for brand-name manufacturers to comply with both federal labeling requirements and state tort law effectively requiring a stronger label. 555 U.S. at 568, 573.

comply with both federal labeling standards and state law requirements deviating from those standards. PLIVA, 131 S. Ct. at 2578.

There is no doubt that Congress wanted to reduce medical costs by spurring generic copycat drugs, and accordingly generic manufacturers do not, after patent protection lapses, need separate FDA approval to manufacture approved drugs or employ their approved labeling. See PLIVA, 131 S. Ct. at 2574, id. at 2582; see also 21 U.S.C. § 355(j)(2)(A). But, as the generic maker cannot alter the labeling, PLIVA held that Congress cannot have wanted the generic to pay damages under state law for a label that the FDA required.

Mutual argues with some force that the generic maker also cannot alter the composition of the drug and so PLIVA's policy of encouraging generics by preempting state tort claims should extend to design defect as well as claims based on inadequate warning. But although Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway), it certainly can choose not to make the drug at all; and the FDCA might permit states to tell Mutual it ought not be doing so if risk-benefit analysis weights against the drug, despite what the Supreme Court made of similar arguments in the labeling context.

This is second-guessing the FDA (unless new information emerged known to the maker but not the FDA), but Wyeth resolved the conflict against general preemption. And, not only has the Supreme Court not yet said it would extend PLIVA's exception to design defect claims, but--while the generic maker has no choice as to label--the decision to make the drug and

market it in New Hampshire is wholly its own. Thus, Bartlett having lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief.

True, such arguments can be turned on their head.[3] To refuse preemption here is consistent with Wyeth but in tension not with the holding but with part of PLIVA's rationale; a generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug; and while PLIVA is itself a limited departure from a general rule of Wyeth, an extension of PLIVA to design defect claims would comprise a general rule for generics (although not one PLIVA expressly adopted).

On balance, we conclude that the Court adopted a general no-preemption rule in Wyeth and that it is up to the Supreme Court to decide whether PLIVA's exception is to be enlarged to include design defect claims. Cf. Khan v. State Oil Co., 93 F.3d 1358, 1362-64 (7th Cir. 1996), vacated and remanded, 522 U.S. 3 (1997). Given the widespread use of generic drugs and the developing split in the lower courts, see note 3, above, this issue needs a decisive answer from the only court that can supply it.

Expert Testimony. Next in the crosshairs are Bartlett's experts--pharmacologist/toxicologist Randall Tackett and burn surgeon Roger Salisbury. Mutual

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[3] Cf. In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig., No. 2:11–md–2226, 2012 WL 718618, at *2-*3 (E.D. Ky. Mar. 5, 2012); Lyman v. Pfizer, Inc., No. 2:09–cv–262, 2012 WL 368675, at *4 (D. Vt. Feb. 3, 2012); In re Pamidronate Prods. Liab. Litig., Nos. 09–MD–2120, 10–CV–1860, 2012 WL 272889, at *3 (E.D.N.Y. Jan. 30, 2012).

argues they were not qualified to offer their opinions, and that the opinions were either unreliable or undisclosed in their expert reports. The governing law is set forth in the Federal Rules of Evidence and Civil Procedure,[4] and Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), which makes the judge the gatekeeper to assure that purported scientific evidence has legitimate basis. We review for abuse of discretion, Milward v. Acuity Specialty Prods. Grp., 639 F.3d 11, 13 (1st Cir. 2011), cert. denied, 132 S. Ct. 1002 (2012), and find none here.

Tackett and Salisbury offered a variety of opinions, the most relevant here relating to sulindac's risks and benefits. The district court found unreliable any explicit opinion that sulindac has a higher risk of causing SJS/TEN than other NSAIDs--what it called an opinion about "relative risk." But otherwise, the district court allowed Bartlett's experts:

> to opine that sulindac's overall risk/benefit profile was unfavorable for marketing
>
> - to opine that aspirin and acetaminophen, which have no known connection to SJS/TEN, are safer alternatives to sulindac
>
> - to discuss voluntary "adverse event reports" (AERs) from prescribing doctors to the FDA, and the limitations of such data

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[4] Fed. R. Evid. 702 (permitting qualified experts with specialized technical knowledge to provide opinions if based on application of reliable principles, methods, and data); Fed. R. Civ. P. 26(a)(2)(B) (expert report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them"); Fed R. Civ. P. 37(c)(1) (prohibiting use of undisclosed information).

- to opine--based on the number of AERs and an estimated number of sulindac prescriptions--on the "reporting rate" of SJS/TEN, and to compare drugs' reporting rates
- to offer various opinions about the inadequacy of sulindac's warning to counteract its dangerousness
- and to opine that the FDA lacks the resources to ensure that all marketed drugs are safe and effective.

Mutual argues that the two experts were not qualified, noting that neither witness ever prescribed an NSAID, and Tackett is not authorized to prescribe any drugs. But Salisbury is a burn surgeon with over 35 years' experience who treated more than 400 patients with SJS/TEN. Tackett is a pharmacologist and pharmacology professor with over 30 years' experience. Both had some experience with the FDA through their 2005 Citizen's Petition requesting an SJS/TEN risk assessment and labeling change for ibuprofen. And their reports demonstrate substantial familiarity with the relevant medical literature.

Alternatively, Mutual argues that the opinions lack scientific basis and were inadmissibly unreliable, focusing on their use of AERs, voluntary reports from medical professionals and consumers to the FDA regarding patients' adverse reactions to pharmaceuticals. The FDA collects this information; and relevant data for sulindac included 89 reports of SJS/TEN from 1980 to 1997, increasing to 134 by 2004; 39 cases of death; and one of the highest SJS/TEN reporting rates among NSAIDs.

Mutual says there are no quality controls on spontaneous reports; that various biases may increase reporting, including increased reporting following introduction of a new warning (a phenomenon called the "Weber effect"); and the difficulty of determining the number of total prescriptions ("denominator data") to determine a reporting rate. The FDA itself warns that "[a]ccumulated case reports cannot be used to calculate incidence or estimates of drug risk." Mutual also argues there is no accepted methodology for comparing drugs based on adverse event data.

But proof that a significant number of adverse reports exists is part of the calculus and surely relevant input for a witness who is prepared to opine on the risk-benefit ratio based on a range of considerations. Mutual's own designated expert, Robert Stern, relied on adverse event data and comparative reporting rates in a peer-reviewed publication designed to quantify the risk of SJS/TEN associated with the use of NSAIDs ("Mockenhaupt 2003"). And the FDA itself considered the SJS/TEN reporting rate of extra--another ..... NSAID--in recommending its withdrawal,and published a study comparing SJS/TEN reporting rates among certain NSAIDs.

As for biases that might distort the level of reporting, these are usually matters to be developed on cross-examination and go to the weight of the evidence unless the biases are so overwhelming as to make the data useless. And, as icing on the cake, at least one well-recognized limitation of adverse event data--underreporting--actually works in Bartlett's favor. Bartlett, 760 F. Supp. 2d at 234. Controlled studies would likely be superior but apparently none were

available to quantify sulindac's incidence of causing SJS/TEN. Id. at 237.

Mutual is correct that in some cases courts found AERs and similar case reports insufficient to establish that a drug caused a certain adverse event, but these involved adverse events with innumerable possible causes (e.g. suicidal behavior, strokes, or birth defects).[5] Here, sulindac is a recognized cause of SJS/TEN and the evidence is that it caused Bartlett's SJS/TEN. Cf. Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 815 n.38 (5th Cir.), cert. denied, 504 U.S. 956 (1992) (10 seizure reports of dubious connection to the drug at issue).

Further, the district court excluded opinions based on what Tackett admitted to be unreliable--namely, a direct comparison of sulindac's risk of SJS/TEN to other NSAIDs (including Bextra). The district court also admonished counsel not to confuse "reporting rates" with "actual incidence rates," and instructed the jury that, while it had heard evidence about sulindac's SJS/TEN reporting rate, it had not heard evidence about the actual rate at which sulindac causes SJS/TEN. But it was at least a sufficient danger that sulindac's labeling, whether adequately or not, warned doctors about it.

Next, Mutual argues that Bartlett's experts failed to account for various shortcomings in adverse event data--for example, that they failed to consider whether the "Weber effect" increased sulindac's adverse event

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[5] E.g., Miller v. Pfizer, Inc., 196 F. Supp. 2d 1062, 1077 (D. Kan. 2002); Siharath v. Sandoz Pharms. Corp., 131 F. Supp. 2d 1347. 1361 (N.D. Ga. 2001); Wade-Greaux v. Whitehall Labs., 874 F. Supp. 1441, 1481 (D.V.I. 1994); DeLuca v. Merrell Dow Pharms., Inc., 791 F. Supp. 1042, 1050-51 (D.N.J. 1992).

reporting; that sulindac's reporting rate in certain years may have been inflated because prescription data had to be approximated; and that Tackett's initial report count was inflated by duplicate reports and reports in which sulindac was not the cause of the adverse effect (Tackett later supplied corrected data).

But these objections were raised mid-trial although apparently known to Mutual much earlier, and Mutual was free to--and did--highlight the flaws on cross-examination. Mutual was also free to develop evidence to show lesser benefits or greater dangers from alternative NSAIDs or similar drugs like acetaminophen. Mutual finally objects that the experts did not testify to the ultimate issue of "unreasonable dangerousness," but that was at the district court's order and was meant to work to Mutual's benefit.

Finally, Mutual argues that the opinions, bases and supporting materials used by Bartlett's experts at trial were not adequately disclosed in the pre-trial disclosures for expert testimony. The original expert reports focused on some issues--labeling and marketing in particular--that were downplayed or dropped as the case was narrowed; but, as the district court declared, "the reports were filled with opinions about sulindac's risks and benefits," the weighing of which determines unreasonable dangerousness and, ultimately, design defect. Bartlett, 760 F. Supp. 2d at 233. So Mutual was hardly ambushed by the main thrust of the experts' testimony.

But Mutual does claim that some important underpinnings were not adequately disclosed in Tackett's expert report which, together with expert depositions, is what allows the other side to prepare its

own experts and effectively cross-examine at trial. Metavante Corp. v. Emigrant Sav. Bank, 619 F.3d 748, 762 (7th Cir. 2010), cert. denied, 131 S. Ct. 1784 (2011). This kind of policing is primarily a matter for the district judge, Gay v. Stonebridge Life Ins. Co., 660 F.3d 58, 64 (1st Cir. 2011), but in extreme cases, appellate review is a backstop, see Licciardi v. TIG Ins. Grp., 140 F.3d 357, 363-64 (1st Cir. 1998).

In this case, Mutual lays special stress on two documents. One concerns a 2005 FDA analysis of NSAID risks (the "Bextra Memo") connected to the ultimate withdrawal of Bextra, a different NSAID, because of undue SJS/TEN risk. Contrary to Mutual's assertion, the Bextra Memo was cited in Tackett's report not merely for the proposition that the FDA had approved NSAID labeling changes; it also was cited to draw comparisons between Bextra and sulindac, and Mutual cannot properly claim to have been ambushed by this use.

More dangerous to Mutual were data relied on by Tackett from a draft report on NSAID SJS/TEN risk, prepared by Robert Stern (who, again, was Mutual's designated expert) for the drug company Pharmacia (the "Pharmacia Report"), in forming his opinion about sulindac's high reporting rate of SJS/TEN. The Pharmacia Report has a storied history in this litigation--with Bartlett faulting Stern for failing to disclose the report during discovery, and the district court ordering supplemental deposition of Stern about it, only to discover that Tackett knew about the report all along.

Tackett at least cited the eventually-published version ("Mockenhaupt 2003") in support of statements in his expert report that "Sulindac had significantly

and substantially higher rates of reported SJS/TEN reactions relative to the office visits compared to other NSAIDs," that "Sulindac ranked in the top 5 of all drugs to cause SJS and TEN between 1980-1997," and "[c]ompared to other NSAIDs Sulindac had a higher reporting rate of SJS and TEN." Although the Pharmacia Report added that sulindac may have had the highest SJS/TEN reporting rate among NSAIDs from 1980 to 1997, neither the report nor Tackett's opinion about sulindac's high SJS/TEN reporting rate were a surprise to Mutual by the time of trial.

Labeling Instructions. Mutual next faults the district court for telling the jury it could "consider the FDA's requirements for drug labels" in determining whether sulindac's warning mitigated its unreasonable dangerousness, and for failing to instruct the jury that Mutual could not legally change sulindac's label. Mutual argues that the jury must have inferred, incorrectly, that it could consider whether Mutual should have improved the warnings. As already explained, under current law the original maker, but not the generic provider, can alter the label.

But the label was relevant to the design defect claim since, although unalterable by Mutual, its arguable inadequacies put limits on the extent to which its dangerousness was offset by adequate warnings; so the lack of a clearer warning made the product itself more dangerous under the risk-benefit test prescribed by Vautour. The district court's instructions, in a section covering "The warning" did make clear that this was the relevance of the label.[6] If

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[6] Mutual directs us to an allegedly contradictory statement by the district court that "[l]iability may exist if the manufacturer did not take available and reasonable steps to lessen or eliminate the

Mutual wanted a further caution in the instructions, it should have sought it.

Of course, at the time of the trial, PLIVA had not yet been decided, so such a caution might not have been at the forefront of Mutual's thoughts. But the legal argument for such a caution was available to Mutual without PLIVA, cf. note 2; indeed, Mutual made this very argument in seeking a new trial before PLIVA was decided. Mutual failed to seek such an instruction before the jury retired; and the instructions given were not plain error.

Counsel's Conduct. In its motion for a new trial, Mutual argued that the conduct of plaintiff's counsel was improper in various respects and that a new trial was justified on this count alone. In a post-trial motion of this sort, our review is for abuse of discretion; and where the charges involve judgments about degrees of impropriety, prejudice and cumulative effect, the trial judge has a special advantage over a reviewing court. Hatfield-Bermudez v. Aldanondo-Rivera, 496 F.3d 51, 64 (1st. Cir. 2007).

Of the many charges, several relating to alleged non- disclosures in the expert reports have already been answered; others are fairly trivial (a rhetorical claim that sulindac "stole" Bartlett's freedom) or had no conceivable impact (a sequestration order violation where Bartlett's husband observed his sister-in-law testify but in the end did not himself appear as a witness). We pass over such issues and focus on those that are potentially more serious.

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danger of even a useful and desirable product." In context, it is clear these statements were made regarding product design and not labeling.

First, in voir dire Bartlett's counsel asked the jury to consider whether it could award "$20 million or more in damages"; but Bartlett's counsel had expressed their intent to mention specific damages figures, and Mutual did not seek to prevent the question in advance. After Mutual objected at voir dire, Bartlett's counsel were prohibited from mentioning total dollar figures again until closing, and the jury was told that any amount mentioned by counsel was "not evidence in this case."[7]

Second, counsel also--despite an order prohibiting discussion of Mutual's financial condition, Bartlett v. Mutual Pharm. Co., No.08-cv-358, 2010 WL 3092649, at *8 Aug. 2, 2010) -- displayed to the jury a silent deposition clip whose captioning indicated Mutual's $480 million sales figure from 2007, before that clip skipped ahead to the next admissible question-and-answer. The parties vigorously dispute whether this was merely accidental, but we accept the district court's judgment that this isolated silent deposition clip, never again mentioned, is not basis enough for a new trial.

Finally, Bartlett's counsel can be faulted in many instances for their manner of offering evidence. Counsel frequently led their own witnesses, although perhaps in some instances to avoid eliciting inadmissible information. Bartlett, 760 F. Supp. 2d at

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[7] In closing, counsel suggested between $20 and $30 million for pain and suffering alone. Although allowing counsel to do so was error under First Circuit precedent, Davis v. Browning-Ferris Indus., Inc., 898 F.2d 836, 837-38 (1st Cir. 1990), Mutual apparently assented to counsel doing so, provided the district court instructed the jury as described, Bartlett, 760 F. Supp. 2d at 254 n.39.

257. Counsel also mischaracterized the record, including in closing argument. Counsel left prejudicial images of Bartlett's injuries visible to the jury for longer than necessary. And counsel attempted to use other demonstrative aids in a misleading manner.

The district court frequently reprimanded counsel, on occasion in front of the jury. Bartlett, 760 F. Supp. 2d at 253. The judge was pro-active when he noticed Bartlett's counsel misusing demonstrative and other visual aids, sometimes intervening even where Mutual had not objected. And in some instances the judge gave curative instructions to limit or erase any prejudice.

In the end, weighing the effect on a verdict of various missteps by counsel is a judgment call, and the district court in denying the motion for a new trial gave reasoned consideration to Mutual's arguments based on individual incidents. Given the comparative strength of Bartlett's expert evidence, the prior instances of sulindac-SJS/TEN events, and the enormous harm wrought in this instance, a judgment that misconduct did not cause the verdict for Bartlett is not unreasonable.

Excessive Verdict. Mutual next argues that the jury's damages award is excessive. A new trial is warranted where the jury award is "grossly excessive, inordinate, shocking to the conscience of the court, or so high that it would be a denial of justice to permit it to stand." Franceschi v. Hosp. Gen. San Carlos, Inc., 420 F.3d 1, 5 (1st Cir. 2005). The facts are taken in the light most favorable to the plaintiff, but nevertheless the figure must be in the "universe of acceptable awards." Blinzler v. Marriott Int'l, Inc., 81 F.3d 1148, 1162 (1st Cir. 1996).

The jury awarded Bartlett $26.01 million--$4.56 million in largely uncontested special damages ($1.25 million past medical expenses, $2.377 million for future medical expenses, and $933,000 for lost wages), and $16.5 million for pain, suffering, and loss of enjoyment of life. All but the last figure rest on specific evidence that the jury accepted; but the last is, of course, the largest number and the target of Mutual's attack.

Mutual says that this is the largest award in New Hampshire history--and more than twice the award against a car manufacturer, following a crash in which a young child died and another was left permanently disabled. Trull v. Volkswagen of Am., Inc., 320 F.3d 1, 3 (1st Cir. 2002), cert. denied, 540 U.S. 938 (2003). Arguably, the more pertinent comparison is to the surviving child Nathaniel who, economic damages aside, was awarded just under $4 million for pain and suffering and other intangible elements of damage. Id. at 9-10.

Nathaniel suffered a skull fracture and bleeding that required an operation to remove the fluid, and his experts opined that the head trauma exacerbated a preexisting condition so that he would have to live indefinitely under supervised and structured conditions. Trull, 320 F.3d at 10. The trauma of the crash, whatever suffering attended recovery from the operation and intangible losses from a more constrained life were thus valued by the jury at about a quarter of the amount awarded to Bartlett for pain and suffering.

Nevertheless, Bartlett's injuries were truly horrific. She spent almost two months in MGH's burn unit, spent months in a medically-induced coma, and

suffered burns over nearly two-thirds of her body. Her burn surgeon described the experience as "hell on earth." She spent a year being tube fed and endured two major septic shock episodes. She suffered through 12 eye surgeries and has many more ahead of her. This is a brief summary of the suffering detailed for the jury.

In addition, the permanent damage is severe. Bartlett cannot eat normally due to esophageal burns, cannot have sexual relations due to vaginal injuries, and cannot engage in aerobic activities due to lung injuries. She is almost blind now and faces some likelihood of complete and permanent blindness. She cannot read or drive or work. And she is seriously disfigured in face and body. In sum, the jury's award is not so clearly disproportionate to the harm suffered that a court must set it aside.

The outcome of this case, at least on this record, is not surprising or, with respect to sulindac, patently alarming. True, that drug has a minuscule risk of causing SJS/TEN, but sulindac is a recognized cause of SJS/TEN--potentially a leader among NSAIDs in that respect--and the drug carries other risks as well. And how far it has advantages over similar medicines with less or no risk is unclear in light of the limited defense offered; at most cross-examination suggested that sulindac may be the only approved NSAID for certain forms of arthritis.

Whether or not our present regime of drug regulation and compensation for harm is optimal is debatable; but the ability of judges to reshape the regime in any fundamental way may be quite limited. As for the trial itself, the district judge handled a very difficult case with skill and insight and he deserves

this court's special thanks for his thoughtful and very helpful opinions.

Affirmed.

United States Court of Appeals
For the First Circuit

No. 10-2277

KAREN L. BARTLETT,

Plaintiff, Appellee,

GREGORY S. BARTLETT, Plaintiff,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Defendant, Appellant,

UNITED RESEARCH LABORATORIES, INC., n/k/a
URL Pharma, Inc.; BROOKS PHARMACY,

Defendants.

JUDGMENT

Entered: May 2, 2012

This cause came on to be heard on appeal from the United States District Court for the District of New Hampshire and was argued by counsel.

Upon consideration whereof, it is now here ordered, adjudged and decreed as follows: The judgment of the district court is affirmed.

By the Court:

/s/ Margaret Carter, Clerk

cc: Mr. Ballew, Mr. Beaupre, Mr. Bogard, Mr. Chabot, Mr. Cosgrove, Ms. Craig, Mr. Friberg, Mr. Geiger, Mr. Geoppinger, Mr. Jensen, Mr. Judge, Mr. Luca, Ms. Maichi, Mr. O'Neal, Mr. Roberson & Mr. Thomas.

United States Court of Appeals
For the First Circuit

No. 10-2277

KAREN L. BARTLETT,
Plaintiff, Appellee,

GREGORY S. BARTLETT,

Plaintiff,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Defendant, Appellant,

UNITED RESEARCH LABORATORIES, INC., n/k/a URL Pharma, Inc.; BROOKS PHARMACY,

Defendants.

ERRATA

The opinion of this Court, issued on May 2, 2012, should be amended as follows.

On page 12, line 8 of 2nd paragraph, "PLIVA" should be underlined.

On page 24, line 1 of 3rd paragraph, replace "$26.01 million" with "21.06 million".

United States District Court, D. New Hampshire

KAREN L. BARTLETT,

Plaintiff, Appellee,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,

Civil No. 08-cv-358-JL

January 5, 2011

OPINION & ORDER

JOSEPH N. LAPLANTE, District Judge.

This products liability case arises out of severe and permanent injuries, including blindness, that plaintiff Karen Bartlett suffered after ingesting sulindac, a prescription drug manufactured by the defendant, Mutual Pharmaceutical Company. Bartlett brought claims against Mutual for strict liability (defective design), strict liability (failure to warn), fraud, and negligence under New Hampshire law. This court granted summary judgment to Mutual on nearly all of the claims. *See Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 135 (D.N.H. 2010) (failure to warn, fraud, and part of negligence claim); *Bartlett v. Mut. Pharm. Co.*, 2010 DNH 164, 2010 WL 3659789, 2010 U.S. Dist. LEXIS 96711 (remainder of negligence claim). Bartlett proceeded to trial and prevailed on her sole remaining claim, for defective design. The jury found

in her favor and awarded her $21.06 million in compensatory damages.

Mutual has now renewed its motion for judgment as a matter of law, *see* Fed. R. Civ. P. 50(b), arguing that Bartlett presented insufficient evidence to support her claim and that the claim is pre-empted by federal law. Mutual has also moved, in the alternative, for a new trial, *see* Fed. R. Civ. P. 59, arguing that numerous errors at trial tainted the jury verdict and that the damages award was excessive. Both motions are denied. Bartlett presented sufficient evidence for a reasonable jury to conclude that sulindac's risks outweighed its benefits, making it a defective product unreasonably dangerous to consumers. Federal law does not prohibit states from imposing liability on that basis. In light of the severe injuries that Bartlett suffered, the damages award (though substantial) was within the acceptable range. And while no three-week trial is perfect, Mutual has not identified any errors that would warrant setting aside the jury verdict or retrying the case.

To a large extent, Mutual's post-trial motions attempt to escape the consequences of its own tactical decisions. For example, Mutual accuses this court of expanding the scope of manufacturer liability for injuries caused by products that cannot be made safer. But Mutual voluntarily withdrew an affirmative defense, recognized by this court in its summary judgment ruling, that would have relieved Mutual of liability if it proved that sulindac was unavoidably unsafe and had an adequate warning. *See Bartlett*, 731 F. Supp. 2d at 151. Mutual also accuses Bartlett of giving the jury an unbalanced view of sulindac's risks and benefits. But Mutual chose not to call any of its

own witnesses at trial, foregoing the opportunity to rebut Bartlett's evidence and put sulindac in a better light. Of course, Mutual was entitled to employ any trial strategy it wished. But, having made those tactical decisions, it must live with the consequences. It is not entitled to another trial where it can try a different strategy.

I. *Applicable legal standard*

"The standard for granting a Rule 50 motion [for judgment as a matter of law] is stringent." *Malone v. Lockheed Martin Corp.*, 610 F.3d 16, 20 (1st Cir. 2010). Courts may set aside a jury's verdict and award judgment as a matter of law "only when the evidence points so strongly and overwhelmingly in favor of the moving party that no reasonable jury could have returned a verdict adverse to that party." *Id.* In making that determination, the court must "view the evidence in the light most favorable to the verdict, making no determination[ ] of [its] own as to the credibility of witnesses or the weight of the evidence." *Rodriguez–Garcia v. Miranda–Marin*, 610 F.3d 756, 765 (1st Cir. 2010). It is the moving party's burden to "specify ... the law and facts that entitle it] to the judgment." *Coons v. Indus. Knife Co.*, 620 F.3d 38, 44 (1st Cir. 2010) (quoting Fed. R. Civ. P. 50(a)(2)).

The standard for granting a motion for new trial under Rule 59 is more flexible. "The district court has the power and duty to order a new trial whenever, in its judgment, the action is required to prevent injustice." *Rodriguez–Garcia*, 610 F.3d at 765. In making that determination, the court "is free to independently weigh the evidence," including "the credibility of the witnesses." *Jennings v. Jones*, 587 F.3d 430, 436 (1st Cir. 2009). But the court "cannot

displace a jury's verdict merely because [it] disagrees" with the outcome. *Id.* A new trial may be granted "only if the verdict is against the law, against the weight of the credible evidence, or tantamount to a miscarriage of justice." *Crowe v. Marchand*, 506 F.3d 13, 19 (1st Cir. 2007). It is the moving party's burden to show that any "errors and defects" at trial affected its "substantial rights." Fed. R. Civ. P. 61; *see also Cabral v. U.S. Dep't of Justice*, 587 F.3d 13, 22 (1st Cir. 2009).

II. *Background*

In December 2004, Bartlett sought medical treatment for pain in her right shoulder. Her doctor prescribed a non-steroidal anti-inflammatory drug ("NSAID") called Clinoril. A nearby pharmacy filled the prescription with sulindac, a generic version of the drug manufactured by Mutual. Within weeks, Bartlett went to the emergency room complaining of skin blisters, eye irritation, and other symptoms. She was soon diagnosed with Stevens–Johnson Syndrome ("SJS") progressing to toxic epidermal necrolysis ("TEN"), a serious and potentially fatal condition characterized by necrosis of the skin and mucous membranes. *See Dorland's Illustrated Medical Dictionary* 1872 (31st ed.2007). Her doctors concluded that the SJS/TEN was caused by sulindac. She spent about three months in the hospital recovering—two of them in a medically induced coma—and emerged with permanent injuries, including blindness.

Bartlett brought suit against Mutual in New Hampshire Superior Court in January 2008, asserting claims for strict liability (defective design), strict liability (failure to warn), fraud, and negligence under New Hampshire law. She had three principal theories

of liability: (1) that Mutual failed to warn adequately about sulindac's risk of SJS/TEN; (2) that Mutual failed to survey the medical literature for information about sulindac's risks and to report that information to the Food & Drug Administration ("FDA"); and (3) that sulindac's risks outweighed its benefits, making it a defective product unreasonably dangerous to consumers. Mutual removed the case to this court, *see* 28 U.S.C. § 1441, which has subject-matter jurisdiction based on diversity of citizenship, *see* 28 U.S.C. § 1332(a)(1).

At first, the litigation focused primarily on Bartlett's failure-to-warn theory. Mutual moved for judgment on the pleadings, *see* Fed. R. Civ. P. 12(c), arguing that the Hatch–Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and related FDA regulations barred a manufacturer from unilaterally changing the warning for a generic drug, which must remain identical to that of the brand-name drug, and therefore pre-empted Bartlett's claims. This court denied the motion, concluding that federal law allowed such changes and did not pre-empt Bartlett's claims. *See Bartlett v. Mut. Pharm. Co.*, 659 F. Supp. 2d 279 (D.N.H. 2009); *accord Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010), *cert. granted*, —— U.S. ——, 131 S. Ct. 817, 178 L.Ed.2d 550 (2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), *cert. granted*, —— U.S. ——, 131 S. Ct. 817, 178 L.Ed.2d 550 (2010).

Mutual then moved for summary judgment, *see* Fed. R. Civ. P. 56, arguing that sulindac's warning was adequate as a matter of law and that, in any event, Bartlett could not prove that any defect in the warning caused her injuries because her doctor admittedly

never read the warning before prescribing sulindac. This court rejected the first argument, finding that the adequacy of sulindac's warning was for the jury to decide (sulindac's label expressly mentioned SJS/TEN in its list of potential adverse reactions, but not in its warnings section). *See Bartlett*, 731 F. Supp. 2d at 143–45. But this court agreed with the second argument, as to the lack of causation, and therefore granted summary judgment to Mutual on Bartlett's claims for strict liability (failure to warn) and fraud, as well as her negligence claim to the extent it was based on a failure-to-warn theory. *Id.* at 145–49.

After that ruling, this court *sua sponte* ordered the parties to brief whether Bartlett had a trialworthy claim for negligence based on her second theory: that Mutual failed to survey the medical literature for information about sulindac's risks and to report that information to the FDA. Bartlett's brief made clear that the theory depended on speculation that the FDA, if advised of that information, would have withdrawn its approval of sulindac in whole or in part, contrary to what had actually happened (sulindac remains on the market to this day, with FDA approval). Accordingly, this court granted summary judgment to Mutual on the remainder of Bartlett's negligence claim. *See Bartlett*, 2010 WL 3659789, at *4–12, 2010 U.S. Dist. LEXIS 96711, at *12–36. As a result, Bartlett also lost any ability to recover enhanced compensatory damages, since her claim for those damages was based on her failure-to-warn and failure-to-survey theories. *Id.*, 2010 WL 3659789, at *12–13, 2010 U.S. Dist. LEXIS 96711, at *36–40.[1]

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[1] Using a similar *sua sponte* procedure, this court also granted summary judgment to Bartlett on certain of Mutual's affirmative

Those rulings left Bartlett with only one theory for trial: that sulindac's risk outweighed its benefits, making it a defective product unreasonably dangerous to consumers. Mutual challenged that theory as well (albeit not until a motion for reconsideration of this court's summary judgment ruling), arguing that New Hampshire law requires a plaintiff to prove, in addition to the product's risks outweighing its benefits, some other "defect" in design. *See Buckingham v. R.J. Reynolds Tobacco Co.*, 142 N.H. 822, 713 A.2d 381 (1998). But this court disagreed, explaining that under more recent New Hampshire Supreme Court cases "a product is defective as designed if the magnitude of the danger outweighs the utility of the product," *Bartlett v. Mut. Pharm. Co.*, 2010 DNH 130, 2010 WL 3239247, at *3, 2010 U.S. Dist. LEXIS 77902, at *7 (quoting *Vautour v. Body Masters Sports Indus., Inc.*, 147 N.H. 150, 154, 784 A.2d 1178 (2001)), and "the plaintiff is not required to present evidence of a safer alternative design," *Bartlett v. Mut. Pharm. Co.*, 2010 WL 3303634, at *1, 2010 U.S. Dist. LEXIS 84924, at *3 (document no. 336) (quoting *Kelleher v. Marvin Lumber & Cedar Co.*, 152 N.H. 813, 831, 891 A.2d 477 (2005)).

Nevertheless, this court agreed with Mutual that if a drug cannot be redesigned to make it safer, the manufacturer's liability must be limited. Following the view set forth in the *Restatement (Second) of Torts* § 402A, *cmt. k* (1965), this court ruled that Mutual could "avoid liability for defective design if it can prove, as an

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defenses that were based on the alleged misconduct of Bartlett and her doctor, concluding that the defenses were not sufficiently supported by the necessary expert testimony. *See Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 184 (document no. 340).

affirmative defense, that sulindac is unavoidably unsafe and had an adequate safety warning." *Bartlett*, 731 F. Supp. 2d at 151; *see also* 1 Louis R. Frumer & Melvin I. Friedman, *Products Liability* § 8.07[5], at 8–296 (2010) (noting that because comment k "is traditionally viewed as an exception and a defense to strict liability, courts generally place the initial burden of proving the various ... factors on the defendant"). Mutual, however, voluntarily withdrew that "comment k" defense on the eve of trial, without explanation. *See* document no. 332.

With Bartlett's failure-to-warn theory and Mutual's "comment k" defense out of the case, the adequacy of sulindac's warning (meaning whether it reasonably informed doctors of the drug's risks, *see Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 657 (1st Cir. 1981))[2] was no longer an issue for trial. Mutual argued that this court should therefore exclude all warning-related evidence and instruct the jury to analyze sulindac's risks and benefits "without regard to the warning." But since a warning can affect a drug's risks and benefits (e.g., by explaining how to use the drug safely, or by identifying certain patients who should not take it), this court concluded that the proposed instruction would provide no real guidance to the jury; either the drug's risks and benefits must be weighed as if it had

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[2] *Brochu* is one of just a handful of decisions, all of them by federal courts, that have applied New Hampshire products liability law to prescription drugs. It is also one of the leading cases establishing that drug manufacturers can be held liable not only on a failure-to-warn theory, but also on a defective design theory. 642 F.2d at 655 (rejecting the view "that under New Hampshire's balancing test no drug can ever be classified as unreasonably dangerous").

no warning at all,[3] or they must be weighed in light of the warning that actually accompanied it. *See Bartlett v. Mut. Pharm. Co.*, 2010 WL 3303864, at *3, 2010 U.S. Dist. LEXIS 102603, at *10 (document no. 345).

Following a line of New Hampshire Supreme Court cases, which expressly stated that the jury in a defective design case may consider "the presence and efficacy of a warning to avoid an unreasonable risk of harm," *Vautour*, 147 N.H. at 154, 784 A.2d 1178, this court ruled that warning-related evidence could be admitted at trial for a limited purpose: if the jury found that sulindac's risks outweighed its benefits, then it could consider whether the warning—regardless of its adequacy—reduced those risks or increased those benefits to such an extent that it eliminated the unreasonable danger. In other words, the warning could operate only to Mutual's benefit. Bartlett needed to prove that sulindac's risks outweighed its benefits "*despite* its warning, not *because* of it." *Bartlett*, 2010 WL 3303864, at *1, 2010 U.S. Dist. LEXIS 102603, at *4.

This court also ruled on many other evidentiary and procedural issues in advance of trial, including nearly 50 challenges to expert witnesses and testimony, *see Bartlett v. Mutual Pharm. Co.*, 2010 DNH 123, 742 F. Supp. 2d 182, 186–87, 2010 WL 2889114, at *1, 2010 U.S. Dist. LEXIS 111959, at *3 (ruling that "[t]he parties' experts have sufficient qualifications and a sufficient foundation to support most of their proffered

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[3] Mutual would not accept this approach as a means of keeping warning-related evidence out of the case. Instead, Mutual wanted the jury to assume that sulindac had the best possible warning, which was contrary to the evidence.

opinions"), and nearly 50 motions in limine, *see Bartlett v. Mut. Pharm. Co.*, 2010 DNH 125, 2010 WL 3156555 (document no. 278) (ruling on Bartlett's limine motions); *Bartlett v. Mut. Pharm. Co.*, 2010 DNH 131, 2010 WL 3092649, 2010 U.S. Dist. LEXIS 111259 (ruling on Mutual's limine motions), as well as Mutual's motion to bifurcate the trial into separate liability and damage phases, *see Bartlett v. Mut. Pharm. Co.*, 2010 WL 3210724 (document no. 320) (denying the motion because bifurcation would result in duplication of evidence and other inefficiencies).

Trial began in August 2010 and lasted nearly three weeks. Bartlett presented testimony from herself, her sister (Barbara Mourikas), two friends who were with her on the day she fell ill (Lynda Mailhot and Rebecca Padulo), eight doctors who treated her for various different injuries resulting from SJS/TEN (primary care physician Leo Lane, burn surgeons Nam Kim, Colleen Ryan, and John Schulz, eye surgeons Claes Dohlman and James Chodosh, pulmonologist Bijan Sadrnoori, and gynecologist Steven Pliskow), two Mutual employees (Robert Dettery and Andria Werynski), two retained expert witnesses who opined about sulindac's risks and benefits (pharmacologist Randall Tackett and burn surgeon Roger Salisbury), and two retained experts who opined about Bartlett's economic damages (economist Thomas Barocci and life care planner Carol Hyland).

Mutual cross-examined Bartlett's witnesses, but chose not to present any witnesses of its own (aside from designating additional testimony by certain unavailable fact witnesses whose testimony Bartlett presented by deposition). At the close of evidence, Mutual moved for judgment as a matter of law, *see*

Fed. R. Civ. P. 50(a)(2), which this court orally denied. On the fourth day of deliberations, the jury returned a verdict in Bartlett's favor, finding that she had proven her claim for strict liability (defective design) by a preponderance of the evidence and awarding her $21.06 million in damages, consisting of $1.25 million for past medical expenses (to which the parties had stipulated), $2.377 million for future medical expenses, $933,000 for lost wages, and $16.5 million for pain, suffering, and loss of enjoyment of life. *See* document no. 381.

This court entered judgment in accordance with the verdict and the earlier summary judgment rulings. *See* document no. 389. Mutual then renewed its motion for judgment as a matter of law, *see* Fed. R. Civ. P. 50(b), arguing that Bartlett presented insufficient evidence to support her claim and that the claim is pre-empted by federal law. Mutual also moved, in the alternative, for a new trial, *see* Fed. R. Civ. P. 59, arguing that numerous errors at trial tainted the jury verdict and that the amount of damages was excessive. The execution of judgment has been stayed pending the resolution of those post-trial motions and any subsequent appeal. *See Bartlett v. Mut. Pharm. Co.*, 2010 WL 4174591, 2010 U.S. Dist. LEXIS 114978 (document no. 406) (applying Fed. R. Civ. P. 62). This court will now analyze each of Mutual's arguments in turn.

III. *Analysis*

A. *Sufficiency of the evidence*

i. Risks outweighing benefits

The first issue raised by Mutual's Rule 50 motion is whether Bartlett presented sufficient evidence for a

reasonable jury to find that sulindac's risks outweighed its benefits. The New Hampshire Supreme Court has stated that, "barring a determination that the utility of the product completely outweighs the risk associated with its use or that the risk of harm is so remote as to be negligible," the weighing of risks and benefits is a "question[ ] of fact to be decided by the jury." *Price v. BIC Corp.*, 142 N.H. 386, 390, 702 A.2d 330 (1997) (citing *Thibault v. Sears, Roebuck & Co.*, 118 N.H. 802, 809, 395 A.2d 843 (1978)).[4] As explained below, this court cannot make either of those risk-benefit determinations as a matter of law in light of the evidence that Bartlett presented. Mutual's challenge to the sufficiency of that evidence is therefore rejected.

As an initial matter, Mutual argues that Bartlett's experts (Drs. Tackett and Salisbury) were not qualified to testify at all about sulindac's risks and benefits, because neither works directly with sulindac and other NSAIDs. "It is not required," however, "that experts be 'blue-ribbon practitioners' with optimal qualifications," *United States v. Vargas*, 471 F.3d 255, 262 (1st Cir. 2006), or that they have "an intimate level of familiarity with every component of a [product] as a prerequisite to offering expert testimony," *Crowe*, 506 F.3d at 18. They need only be "qualified as an expert by knowledge, skill, experience, training, or education." Fed. R. Evid. 702; *see also Levin v. Dalva Bros., Inc.*, 459 F.3d 68, 78 (1st Cir. 2006) ("Rule 702 has been interpreted liberally in favor of the admission of expert testimony.").

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[4] State law governs the sufficiency inquiry in a diversity case. *See, e.g., Soto-Lebron v. Fed. Express Corp.*, 538 F.3d 45, 55 (1st Cir. 2008).

Both of Bartlett's experts easily met that standard. Dr. Tackett has been a pharmacologist for more than 30 years and is a pharmacology professor at the University of Georgia. Dr. Salisbury has been a burn surgeon for more than 35 years and has treated more than 400 patients with SJS/TEN. Both have demonstrated familiarity with the medical literature on sulindac's risks and benefits, as well as NSAIDs and SJS/TEN more generally. They were qualified to testify on those topics. *See Bartlett*, 742 F. Supp. 2d at 198–99, 2010 WL 2889114, at *13, 2010 U.S. Dist. LEXIS 111959, at *36–38 (deeming Drs. Tackett and Salisbury qualified before trial); *Lofton v. McNeil Consumer & Specialty Pharms.*, No. 05–cv1531, 2008 WL 4878066, at *9–10, 2008 U.S. Dist. LEXIS 94391, at *28–30 (N.D. Tex. July 25, 2008) (allowing them to testify in a similar case involving an NSAID that allegedly caused SJS/TEN, citing their "extensive experience").

Mutual also argues that Bartlett's experts should have been prohibited from testifying about sulindac's risks and benefits because their expert reports—like much of the early litigation—focused primarily on Bartlett's failure-to-warn theory, not her defective design theory. *See* Fed. R. Civ. P. 26(a)(2)(B)(I) (requiring pre-trial disclosure of "all opinions that the witness will express"). But the reports were filled with opinions about sulindac's risks and benefits, which were clearly relevant to the defective design theory as well. "The purpose of expert reports is to ... convey the substance of the expert's opinion ... so that the opponent will be ready to rebut [and] cross examine." *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 762 (7th Cir. 2010). Bartlett's expert reports

accomplished that purpose, as evidenced by Mutual's "able cross-examination" of the experts at trial. *Id.*

Mutual notes that Bartlett's experts never opined that sulindac was "unreasonably dangerous," which is the ultimate issue in a defective design case. That is true; this court prohibited them from using that particular phrase at trial because they had not used it in their expert reports. But they did expressly state in their reports, and testify at trial, that sulindac's risks outweighed its benefits, which is what the phrase "unreasonably dangerous" means in this context. *See Vautour*, 147 N.H. at 154, 784 A.2d 1178. There is no requirement that experts utter the magic words "unreasonable danger" for a plaintiff to recover for defective design.[5] *Cf. Kelleher*, 152 N.H. at 832, 891 A.2d 477 (rejecting "the defendant's assertion that the plaintiff was required to use the exact phrase, 'unreasonably dangerous,' to adequately plead" a defective design claim).

As for the opinion that sulindac's risks outweighed its benefits, Mutual argues that it was merely a "passing reference, without support." But Bartlett's experts supported the opinion with a litany of specific facts, most of them drawn directly from the medical literature or published FDA analyses. They testified, for example, to the following:

· ***Causation of SJS/TEN.*** Sulindac is one of many drugs, including nearly every NSAID and nearly every antibiotic, that can cause SJS/TEN. This causal

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[5] Indeed, before this court granted summary judgment on Bartlett's negligence claim, Mutual argued—successfully—that no expert should be allowed to utter the word "negligent." *See Bartlett*, 742 F. Supp. 2d at 198, 2010 WL 2889114, at *12, 2010 U.S. Dist. LEXIS 111959, at *35–36.

link has been confirmed by positive re-challenges, i.e., cases where patients who had previously developed SJS/TEN after taking sulindac developed it again after re-administration of the drug. *See, e.g.*, Glen D. Park et al., *Serious adverse reactions associated with sulindac,* 142 Archives of Internal Medicine 1292–94 (1982).[6]

• ***Background rate of SJS/TEN.*** The background rate of SJS associated with drug therapy is 1.2 to 6 per million prescriptions, and the background rate of TEN (the more serious form of the disease) is 0.4 to 1.2 per million prescriptions, according to FDA estimates. *See* Letter from Steven K. Galson, Director, FDA Center for Drug Evaluation & Research, to Dr. Salisbury, at 5 (June 22, 2006) (document no. 310–1) (citing medical literature).

• ***Group risk of SJS/TEN.*** While no controlled study has measured its individual risk of SJS/TEN, sulindac is part of a group of NSAIDs, known as acetic acid NSAIDs, that has been shown to have a greater risk of SJS/TEN than another group, known as propionic acid NSAIDs, in a controlled study. *See* Maja Mockenhaupt et al., *SJS and TEN: assessment of medication risks with emphasis on recently marketed drugs; the EuroSCAR-study,* 128 Journal of Investigative Dermatology 35, 41 (2008). In addition, sulindac is one of the NSAIDs with longer half-lives, which are suspected of having a greater risk of SJS/TEN because they stay in the body longer. *See,*

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[6] Bartlett's experts were permitted to express opinions based on the medical literature, *see* Fed. R. Evid. 703, but the articles themselves were not admitted as exhibits because they were hearsay not subject to any identified exception, *see* Fed. R. Evid. 801–803.

e.g., Pierre E. Wolkenstein et al., *Drug-induced TEN*, 16 Clinics in Dermatology 399, 403 (1998).

• ***Adverse event reports of SJS/TEN.***[7] From 1980 to 1997, the FDA's adverse event reporting database—which collects spontaneous reports of drug side effects from doctors, manufacturers, patients, etc.—received 89 reports of SJS/TEN attributed to sulindac, more than the number of reports for any other NSAID on the market and all but four drugs of any kind. *See* Maja Mockenhaupt et al., *The risk of SJS and TEN associated with NSAIDs: a multinational perspective*, 30 Journal of Rheumatology 2234 (2003) (document no. 230–4). Through 2004, the number of SJS/TEN reports attributed to sulindac had increased to 134.[8] In 39 of those cases, the patient

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[7] Consistent with a pre-trial ruling, this court allowed Bartlett's experts to "testify based on the [adverse event] reports," *Bartlett*, 2010 WL 3092649, at *1, 2010 U.S. Dist. LEXIS 111259, at *1–4, but excluded the reports themselves from evidence because they were hearsay not subject to any identified exception, *see* Fed. R. Evid. 801–803. The pre-trial ruling left open the possibility that the reports themselves could be admitted to show notice to Mutual (i.e., not for their truth), but that became irrelevant once Bartlett's negligence claim was dismissed. Mutual seems to misunderstand that ruling as limiting the experts' reliance on adverse event reports to notice issues, which by its plain language it did not.

[8] Bartlett's experts originally miscounted the number of reports at 176, which included many duplicates. They corrected the number at trial. This court instructed the jury that it could draw an inference against Dr. Tackett's credibility because he failed to disclose the errors before trial. Mutual argues that this court should have gone further and excluded all of the experts' testimony as unreliable. But, as this court explained in rejecting Bartlett's pre-trial motion to exclude one of Mutual's experts who made a computational error, such errors generally go to the weight, not the admissibility, of expert testimony. *See Bartlett*, 742 F. Supp. 2d at 196–97, 2010 WL 2889114, at *11, 2010 U.S.

died. According to FDA estimates, more than 90 percent of adverse events go unreported.

• ***Reporting rate of SJS/TEN.*** Sulindac's rate of SJS/TEN reports from 1980 to 1997, per million prescriptions, was the highest of any NSAID, according to an unpublished manuscript (document no. 230–2) prepared for the drug company Pharmacia by the authors of the *Journal of Rheumatology* article just mentioned (one of whom was Mutual's own expert, dermatologist Robert Stern).[9]

• ***Risks other than SJS/TEN.*** According to a recent FDA analysis, there is no evidence that any one NSAID—including sulindac—is more or less risky than other NSAIDs with regard to various other known side effects, including gastrointestinal bleeding, renal toxicity, hepatic enzyme elevation, bronchospasm, fluid retention, and edema. *See* John K. Jenkins, Director, FDA Office of New Drugs, *Analysis and recommendations for Agency action regarding NSAIDs*

Dist. LEXIS 111959, at *30–31 (citing cases). Moreover, even without their own count, Bartlett's experts had an independent and reliable basis for testifying about sulindac's high number of SJS/TEN reports: the *Journal of Rheumatology* article. If anything, the errors helped Mutual by giving it a way to counter that evidence (which is presumably why Mutual waited until trial to expose the errors, rather than seeking exclusion when it, too, noticed them before trial).

[9] Mutual argues that Bartlett's experts failed to disclose this opinion in their expert reports. *See* Fed. R. Civ. P. 26(a)(2)(B)(i). But Dr. Tackett expressly stated in his report that the authors of the *Journal of Rheumatology* article "found when analyzing the number of reports per physician office visits with a prescription, sulindac had significantly and substantially higher rates of reported SJS/TEN reactions ... compared to other NSAIDs." So the opinion was disclosed.

and cardiovascular risk 12 (Apr. 6, 2005) (document no. 309–1).[10]

• ***Benefits.*** Sulindac has been approved by the FDA for treatment of acute painful shoulder and various arthritic conditions (acute gouty arthritis, rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis). It is the only NSAID approved to treat the first two conditions. Nevertheless, according to a recent FDA analysis, there is no evidence that any one NSAID—including sulindac—provides greater relief of pain and inflammation than other NSAIDs. *See* Jenkins, *supra,* at 2.[11]

• ***Risk/benefit profile.*** The FDA has recommended that five NSAIDs be removed from the market due, in part, to their risk of SJS/TEN as demonstrated by adverse event reports (sometimes fewer than 15). While sulindac has not been removed from the market, it has a similar "risk/benefit profile" to valdecoxib (known by the brand name Bextra), one of the removed NSAIDs, in that neither drug has a demonstrated advantage over other NSAIDs with

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[10] This court admitted the FDA analysis into evidence as a full exhibit, since it was a self-authenticating public record available on the FDA's website. *See* Fed. R. 803(8) (hearsay exception) and 902 (self-authentication).

[11] Mutual argues that Bartlett's experts failed to disclose this opinion and the one discussed in the previous paragraph. *See* Fed. R. Civ. P. 26(a)(2)(B)(I). But both experts expressly cited the FDA's analysis in their reports and quoted its statement that Bextra, another NSAID, lacked "any demonstrated advantage over other NSAIDs." Their reports then stated that sulindac had a similar "risk/benefit profile" to Bextra. So Mutual was on notice that Bartlett's experts would testify, based on the FDA's analysis, that sulindac also lacked any demonstrated advantage over other NSAIDs.

regard to their benefits or various known risks other than SJS/TEN, *see id.* at 2, 12, both drugs had a higher reporting rate of SJS/TEN than other NSAIDs, *see id.* at 7, and sulindac had more reported deaths from SJS/TEN (39) than did Bextra (7), *see id.*[12]

• ***Safer alternative products.*** Two alternatives to sulindac, aspirin and acetaminophen (known by the brand name Tylenol), carry no risk of SJS/TEN, at least in adults,[13] and are equally effective as sulindac, at least in treating conditions like shoulder pain (for which Bartlett took sulindac). While they carry some additional risks that sulindac does not (e.g., aspirin can cause Reye's syndrome) and may not be equally effective in treating every condition that sulindac treats, they also provide additional benefits that sulindac does not. Overall, they are safer alternative products.

Mutual faults Bartlett's experts for focusing primarily on sulindac's risk of SJS/TEN and failing to consider all of its other risks and its benefits. As just mentioned, however, Bartlett's experts (while

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[12] Mutual argues that this Bextra comparison should have been excluded as unreliable because, as Bartlett's experts acknowledged, Bextra had been on the market for a much shorter period of time (about 3.5 years, compared to sulindac's then–27) and had more SJS/TEN reports (189) than sulindac (133). But those differences went to the weight of the comparison, not its admissibility. The jury could weigh both the similarities and the differences between Bextra and sulindac.

[13] Dr. Tackett acknowledged on cross-examination that a recent study indicated a possible link between Tylenol and SJS/TEN in children. *See* Natacha Levi et al., *Medications as risk factors of SJS/TEN in children: a pooled analysis*, 123 Pediatrics 297 (2009).

acknowledging sulindac's approved uses) testified broadly that there is no evidence that sulindac has any greater benefit than other NSAIDs, or any lesser risk of various known side effects other than SJS/TEN. They based that testimony on a recent FDA analysis, *see* Jenkins, *supra*, at 2, 12, which resulted from what the FDA called "a comprehensive review of the risks and benefits, including the risks of SJS and TEN, of all approved NSAID products," Galson, *supra*, at 2, and which was admitted into evidence as a full exhibit. So their risk/benefit analysis was sufficiently comprehensive.[14]

Mutual argues that this court should have prohibited Bartlett's experts from relying on the FDA's analysis, in light of their testimony that the FDA has insufficient resources to monitor the safety of all drugs, which is how Bartlett's experts attempted to downplay the FDA's approval of sulindac. *See Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 1202, 173 L.Ed.2d 51 (2009) (noting that "FDA has limited resources to monitor the 11,000 drugs on the market" and that, as discussed in Part III.B.i, *infra*, FDA approval does not preclude state tort liability). That was indeed a theoretical tension in Bartlett's case, and one that Mutual highlighted for the jury during closing argument.[15] But it went to the weight, not the

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[14] Bartlett's experts also relied on another piece of evidence that contained an extensive summary of sulindac's risks and benefits, and that was admitted into evidence as a full exhibit: sulindac's label, or "package insert." The label described in detail each of sulindac's approved uses, including the benefits it had been shown to have in controlled studies, and each of its known side effects other than SJS/TEN, including their estimated rates of occurrence.

[15] Of course, Mutual faced the opposite theoretical tension:

admissibility, of the experts' opinions. A reasonable jury could have agreed with Bartlett's experts that the FDA was right about some things, but wrong about others.[16]

If Mutual had evidence to refute the FDA's analysis, such as evidence that sulindac is more beneficial than other NSAIDs or that it has less risk of certain side effects other than SJS/TEN, then Mutual could have presented that evidence at trial in its own case (or, at the very least, confronted Bartlett's experts with it). A plaintiff bringing a claim for defective design cannot be expected to sing the praises of the allegedly defective product, or to put the product in the best possible light. So far as this court can tell, Mutual chose not to present its own experts because it feared that they would actually strengthen, not weaken, Bartlett's case.[17]

Next, Mutual argues that Bartlett presented insufficient evidence for the jury to evaluate sulindac's

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attacking the FDA's recent analysis of NSAIDs as unreliable, while simultaneously emphasizing the FDA's approval of sulindac to suggest it was not unreasonably dangerous.

[16] Mutual also argues that Bartlett's experts lacked a reliable basis for testifying about the FDA's limited resources. But their testimony was based primarily on two government reports, *see* U.S. Gov't Accountability Office, GAO–06–402, *Improvement Needed in FDA's Postmarket Decision-making and Oversight Process* (2006); H. Subcomm. on Science and Technology, *FDA Science and Mission at Risk* (2007), which were admitted into evidence as full exhibits, *see* Fed. R. Evid. 803(8) (hearsay exception) and 902 (self-authentication); *see also* Fed. R. Evid. 703 (permissible bases of expert testimony).

[17] Indeed, one of Mutual's designated experts, Dr. Stern, coauthored the *Journal of Rheumatology* article, on which Bartlett's experts relied, that noted sulindac's high number and rate of SJS/TEN reports.

risk of SJS/TEN. As just mentioned, however, Bartlett's experts testified at length on that issue, opining that sulindac has been confirmed to cause SJS/TEN; that the background rate of SJS/TEN is as many as six cases per million prescriptions; that sulindac is part of two groups of NSAIDs (acetic acid NSAIDs and longer half-life NSAIDs) believed to have a higher risk of SJS/TEN; that the FDA received 133 reports of SJS/TEN attributed to sulindac over the last 25 years; that 39 of those reported cases resulted in death; that sulindac had both a higher number, and a higher rate, of reported cases than any other NSAID from 1980 to 1997 (and the fifth-most of any drug); and that some alternatives to sulindac carry no risk of SJS/TEN.

Mutual argues that this court should have prohibited Bartlett's experts from relying on adverse event reports, since such reports are anecdotal, sometimes unverified or incomplete, and can be influenced by non-random factors.[18] "To be sure, [both parties] agree that adverse event reports—whether published in safety databases or the medical literature—have significant limitations." *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 153 (D. Mass. 2009) (Saris, J.). For precisely the reasons that Mutual cites, they "do not provide as much information as controlled epidemiological studies do." *Id.* (quoting *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1254–54 (11th Cir.

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[18] One such influence, which Bartlett's experts acknowledged at trial, is known as the "Weber effect." *See* J.C.P. Weber, *Epidemiology of adverse reactions to NSAIDs*, 6 Advances in Inflammation Research 1–7 (1984) (finding that adverse event reporting peaks about two years after a drug enters the market).

2005), and also citing *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1040 (D. Minn. 2007), both of which excluded expert testimony based on adverse event reports).

As in many cases involving rare side effects, however, no controlled study of sulindac's SJS/TEN risk is currently available. Under such circumstances, "[c]ourts may, and often do, rely on ... adverse event data" to inform the analysis of a drug's risks. *Id.* at 153 (citing *In re PPA Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003)); *see also, e.g., In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 200 (S.D.N.Y. 2009) (noting that the admissibility of such data "may depend on case-specific circumstances," and stressing the "rarity" of the disease and the "relatively high number" of reports as reasons for admitting it). Despite its limitations, such data has significant probative value and is "reasonably relied upon by experts in the [pharmacological] field in forming opinions and inferences." Fed. R. Evid. 703.

Indeed, Mutual's own designated expert Dr. Stern (and his co-authors) expressly relied on adverse event data in their peer-reviewed *Journal of Rheumatology* article on "The risk of SJS/TEN associated with NSAIDs," which served as the basis for much of Bartlett's expert testimony on this issue. *See, e.g.*, Mockenhaupt 2003, *supra*, at 2238 ("To identify NSAID[s] widely used in the U.S. ... that have risks of SJS and TEN comparable to those of piroxicam [which had a "high risk" in a controlled study], we compared spontaneous reporting rates for all NSAID[s]," per million prescriptions, and "identified four NSAID[s] ... with spontaneous reporting rates comparable to those

of piroxicam: diflunisal, *sulindac,* oxaprozin, and etodolac.") (emphasis added).[19]

The FDA also expressly relied on adverse event data in its recent risk/benefit analysis of NSAIDs. *See, e.g.*, Jenkins, *supra,* at 17 (noting that the "reporting rate of [SJS/TEN] appears to be greater for Bextra than other" NSAIDs). This court is not prepared to deem it unreasonable, as a matter of law, for Bartlett's experts to have done the same thing that a peer-reviewed medical journal, Mutual's own expert, and the FDA have all done. *See, e.g., Crowe,* 506 F.3d at 18 ("Rule 703 was enacted in part 'to bring the judicial practice into line with the practice of the experts themselves when not in court.' ") (quoting Fed. R. Evid. 703, advisory committee notes (1972)); *Ramirez v. Debs–Elias,* 407 F.3d 444, 449 (1st Cir. 2005) (scholarly literature is information reasonably relied upon by medical experts").

It is important to note, moreover, that Mutual extensively cross-examined Bartlett's experts about the limitations of adverse event data, and this court also took a number of steps to prevent them from overstating its significance as a measure of a drug's risk. The experts were required, for example, to use the phrase "reporting rate" in describing adverse event data, rather than "incidence rate," "occurrence rate," "rate" alone, or "relative risk."[20] This court also gave a

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[19] As this quotation makes clear, there is no basis for Mutual's assertion that "the [unpublished] Pharmacia report's conclusion about sulindac's reporting rate was, essentially, abandoned by Dr. Stern and his co-authors in [their] subsequent, peer-reviewed article." The article expressly mentioned that sulindac had one of the five highest reporting rates among NSAIDs.

[20] This court orally vacated a pre-trial ruling to the extent that it

strong cautionary instruction to the jury, both during the expert testimony and again in the final jury charge:

> You have heard testimony about the alleged number of adverse event reports of SJS/TEN associated with sulindac and other drugs, and about their alleged "reporting rates." In the context of this trial, a "reporting rate" means the number of adverse event reports for a drug divided by the number of prescriptions for a drug. You should not confuse "reporting rate" with the rate at which SJS/TEN actually occurs with a drug. Those are two different concepts. You have not heard any testimony about the actual occurrence rate of SJS/TEN with sulindac individually, as compared with other individual drugs, except for those drugs that allegedly do not have any risk of SJS/TEN.

Document no. 378, at 18.

Mutual argues that, without any evidence of sulindac's actual incidence rate of SJS/TEN, the jury had no reasonable basis to "quantify" the risk. But that assumes that the only way to quantify risk is through a controlled study of the individual drug (Bartlett's experts did testify about a controlled study of acetic acid NSAIDs as a group, which found a higher risk of

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would have allowed Bartlett's experts to testify about "relative risk" based on adverse event reports. *See Bartlett*, 742 F. Supp. 2d at 199–200, 2010 WL 2889114, at *14, 2010 U.S. Dist. LEXIS 111959, at *40–41. Mutual complains that this court nevertheless allowed Bartlett's experts to compare sulindac's "risk-benefit profile" to that of Bextra based, in part, on such reports. As this court explained in front of the jury, however, "risk/benefit profile" means the available information on "all risks and all benefits," not the incidence rate of SJS/TEN in particular. To the extent that there may have been any confusion on that point, this court cured it with the cautionary instruction set forth *infra*.

SJS/TEN), and hence that a plaintiff cannot prevail without such a study. It is easy to understand why Mutual would prefer such a requirement, since controlled studies can be hard for plaintiffs to come by, especially for side effects as rare as SJS/TEN. But this court is not persuaded that the New Hampshire Supreme Court would set the bar so high. *Cf. Vautour*, 147 N.H. at 157, 784 A.2d 1178 (allowing jury to make risk/benefit determination despite limitations in expert testimony).

Bartlett's experts quantified sulindac's risk of SJS/TEN in other ways. They testified, for example, that the FDA received 133 reports of SJS/TEN attributed to sulindac over the past 25 years, 39 of which resulted in death, and that more than 90 percent of cases go unreported, according to FDA estimates. From that testimony, the jury reasonably could have inferred that sulindac probably caused more than a thousand cases of SJS/TEN, and hundreds of deaths, over the past 25 years (roughly 50 cases and 15 deaths per year). That is enough quantification to enable a risk/benefit analysis, even if the jury inferred a very high number of prescriptions for sulindac.[21] While the jury certainly could have drawn other inferences from the data, or rejected some of the data for the reasons argued by Mutual, that was not the only rational approach permitted by the evidence.

Next, Mutual argues that sulindac's risk of SJS/TEN is simply too remote to result in liability for defective design. As support for that argument, Mutual invokes dicta from an old New Hampshire Supreme

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[21] Dr. Tackett testified that, at one time (1987), sulindac had been the 44th-most prescribed drug in the country, but that it had been prescribed less in other years.

Court case that "in the absence of adequate warning a one-in-a-million risk of adverse reaction" to a drug is not "a sufficient basis on which to impose strict liability." *Thibault*, 118 N.H. at 808, 395 A.2d 843 (citing *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968), a failure-to-warn case). As that quote suggests, however, *Thibault* actually made that comment in reference to failure-to-warn claims, not defective design claims. *See also Price*, 142 N.H. at 390, 702 A.2d 330 (citing *Thibault's* comment in a defective design case, but with a "*cf.*" signal, meaning that the case supported a different but analogous proposition).[22] The fact that a manufacturer need not have warned of a particular risk does not necessarily mean that the risk did not render its product unreasonably dangerous.

But even accepting *arguendo* Mutual's premise that a "one-in-a-million risk of adverse reaction" to a drug is never actionable under a defective design theory, and its further premise that the jury had no basis for concluding that sulindac's SJS/TEN risk was any greater than the background rate for all drugs,

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[22] Indeed, the "one-in-a-million" comment has been incorporated into New Hampshire's standard jury instruction for failure-to-warn claims. *See* Walter L. Murphy & Daniel C. Pope, *New Hampshire Civil Jury Instructions*, § 23.4, at 23–5 (2007) ("This does not mean that a manufacturer must warn a user/consumer of a one-in-a-million chance of injury."). Mutual argues, in its Rule 59 motion, that this court erred by refusing to give that instruction. But there was no failure-to-warn claim left in the case, and this court specifically instructed the jury (at Mutual's request) that Mutual's conduct in responding to sulindac's risks was "not at issue" in the case. Document no. 378, at 22. Giving the jury part of the failure-to-warn instruction, and thereby suggesting that "a manufacturer must warn a user/consumer of" certain risks, would have been inconsistent and confusing.

Mutual's conclusion still does not follow: per the FDA, even the background rate of SJS/TEN is greater than one-in-a-million, and the top end of the range is six-in-a-million, or one in less than 175,000. (Mutual appears to be ignoring the SJS rate and looking solely at the rate for the more serious TEN, which is lower, but still exceeds one-in-a-million at the top end.) So even if the risk-benefit analysis were strictly a quantitative mathematical calculation, without any qualitative component involving the severity of the side effect, Mutual would not be entitled to judgment as a matter of law on that basis.

Of course, the risk/benefit analysis is not just a mathematical calculation. Even with perfect information about all of sulindac's risks and benefits, no mathematical formula could determine to a legal certainty how many cases of SJS/TEN, how many deaths, how many losses of sight, or how many severe skin burns is a reasonable price to pay for the relief of shoulder pain, arthritis, and other conditions that sulindac provides. It is, at bottom, a judgment call on which reasonable people could disagree. As the New Hampshire Supreme Court has explained, making those sorts of difficult risk/benefit judgments "is the very essence of the jury's function." *Vautour*, 147 N.H. at 157, 784 A.2d 1178; *see also* 2 Frumer & Friedman, *supra*, § 11.03[4][d], at 11–101 ("The determination of a product's risks and benefits as a matter of law ... will rarely be granted in design defect cases if any of the elements is disputed.").

Again, under New Hampshire law, courts may override the jury's risk/benefit judgment in only two circumstances: where "the risk of harm is so remote as to be negligible," or where the "the utility of the

product completely outweighs the risk." *Price*, 142 N.H. at 390, 702 A.2d 330. Neither circumstance is present here. While certainly remote, sulindac's risk of SJS/TEN cannot be considered "negligible," particularly given the severity of the disease and the estimated number of cases and deaths. *See Webster's Third New International Dictionary* 1514 (2002) (defining negligible to mean "of so little consequence as to require or deserve little or no attention: trifling"). And while reasonable people could certainly conclude that sulindac's benefits outweigh its risks, the comparison is not so "completely" one-sided that no one could reasonably conclude otherwise.[23]

In sum, Mutual has not met the "stringent" standard for relief under Rule 50. *Malone*, 610 F.3d at 20. Viewing the evidence in the light most favorable to the verdict, this court concludes that Bartlett presented sufficient evidence for a reasonable jury to find that sulindac's risks outweighed its benefits, making it an unreasonably dangerous product. Mutual has not shown any errors or defects in the admission of that evidence that would entitle it to relief under Rule

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[23] Mutual argues that Bartlett's experts conceded that sulindac's benefits outweighed its risks by testifying that, if not removed from the market, sulindac should at least be reserved for patients who fail to respond to alternative treatments, rather than being used as a "first-line therapy." At most, however, that means that sulindac's benefits might outweigh its risks for a certain subset of patients. Under New Hampshire law, a product's design must "meet risk-utility balancing standards as seen from the point of view of the *public as a whole*," not just a subset of it. *Price*, 142 N.H. at 389, 702 A.2d 330 (emphasis added). Moreover, the jury was free to disregard what was essentially the experts' "backup" position. *See* document no. 378, at 6 (instructing the jury, without objection, that "[y]ou may accept all, part, or none of the testimony of an expert").

59 either. The evidence supporting the jury's verdict was sufficiently reliable to be admitted into evidence, *see, e.g.*, notes 8, 12, 16, and 19, *supra*, and was properly disclosed to Mutual before trial where required, *see, e.g.*, notes 9 and 11, *supra*. Mutual has not suffered anything "tantamount to a miscarriage of justice." *Crowe*, 506 F.3d at 19.

ii. Safer alternative design

The next issue raised by Mutual's Rule 50 motion is whether, in addition to proving that sulindac's risks outweighed its benefits, Bartlett needed to prove that sulindac had some other "defect" in design. Mutual argues that proof of some other "defect" is required by *Buckingham*, 142 N.H. at 822, 713 A.2d 381, and that Bartlett could not satisfy that requirement because sulindac is incapable of being designed any other way.[24] This court has already analyzed that argument at length in two prior orders. *See Bartlett*, 2010 WL 3239247, 2010 U.S. Dist. LEXIS 77902; *Bartlett*, 2010 WL 3303634, 2010 U.S. Dist. LEXIS 84924. As explained there, while *Buckingham* arguably supports Mutual's position, two more recent cases from the New Hampshire Supreme Court make clear that "a product is defective as designed if the magnitude of the danger outweighs the utility of the product," *Vautour*, 147 N.H. at 154, 784 A.2d 1178, and that "the plaintiff is

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[24] Mutual also objects to this court's use of the phrase "defective condition," rather than "defect," throughout the final jury charge. But the New Hampshire Supreme Court commonly uses the phrase "defective condition" when setting forth the elements of a defective design claim, *see, e.g., Vautour*, 147 N.H. at 154, 784 A.2d 1178, and so do New Hampshire's model jury instructions, *see* Murphy & Pope, *supra*, §§ 23.1 and 23.2. Indeed, even Mutual's proposed instructions repeatedly used that phrase. *See* document no. 254, at 4.

not required to present evidence of a safer alternative design," *Kelleher*, 152 N.H. at 831, 891 A.2d 477.

As a federal court exercising diversity jurisdiction over a state-law action, this court "must apply the most recent statement of state law by the state's highest court." *Vitkus v. Beatrice Co.*, 127 F.3d 936, 941–42 (10th Cir. 1997); *see also, e.g., Brunner v. Hampson*, 441 F.3d 457, 465 (6th Cir. 2006); *Lamarque v. Mass. Indem. & Life Ins. Co.*, 794 F.2d 194, 196 (5th Cir. 1986); *Middle Atl. Utils. Co. v. S.M.W. Dev. Corp.*, 392 F.2d 380, 384 (2d Cir. 1968); *cf. Smith v. F.W. Morse & Co.*, 76 F.3d 413, 429 (1st Cir. 1996) (following the more "recently decided" New Hampshire Supreme Court case that "speaks directly to the question," rather than an older opinion). Thus, even assuming *arguendo* that the earlier *Buckingham* decision conflicts with *Vautour* and *Kelleher*, this court must follow the express language of the more recent cases.

Mutual, taking its rhetoric to new heights (or perhaps new lows), describes this court's reading of *Vautour* and *Kelleher* as "bizarre" and "tortured." But Mutual still has not been able to explain how, under its reading of those cases, a plaintiff could prove a "defect" without having to prove some safer alternative design. Mutual's position appears to be that, as stated at the final pre-trial conference, "there has to be an alternative [design]; you just don't have to prove up the alternative." Document no. 302, at 46. Proof, though, is all that counts in determining a plaintiff's *prima facie* burden. And *Vautour* expressly states that "[t]he plaintiffs' burden was to present evidence regarding the risk-utility factors; they did not have a burden of proving a safer, alternative design."[25] 147 N.H. at 154,

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[25] In its post-trial motions, Mutual resorts to dicta from the

784 A.2d 1178; *see also id.* at 157, 784 A.2d 1178 ("plaintiffs presented sufficient evidence that the [product] was unreasonably dangerous pursuant to the risk-utility balancing test"). As discussed in Part III.A.i, *supra*, Bartlett satisfied that burden.

Mutual also describes this court's reading of *Vautour* and *Kelleher* as an act of "social engineering" and predicts that, if plaintiffs can recover for defective design even where a product is unavoidably unsafe and has an adequate warning, no "prudent manufacturer would sell any product in New Hampshire."[26] Mutual seems to have forgotten, however, that this court ruled that Mutual would "avoid liability for defective design if it can prove, as an affirmative defense, that sulindac is unavoidably unsafe and had an adequate safety warning." *Bartlett*, 731 F. Supp. 2d at 151. That is the very limitation for which Mutual has been advocating (albeit in the form of a defense, not a *prima facie* burden). It was Mutual, not this court, that "engineered" a broader scope of liability by voluntarily withdrawing that defense on the eve of trial. *See*

Superior Court decision in *Vautour* in an unpersuasive attempt to demonstrate that the New Hampshire Supreme Court meant something other than what it expressly said. If anything, that approach strikes this court as the more unusual one, particularly where the Supreme Court reversed the Superior Court decision.

[26] As this court previously observed, Mutual's position is itself a call for social policymaking, in that it "would have the practical effect of immunizing nearly all drug manufacturers from [defective design] liability, no matter how dangerous the drug, no matter how minimal its benefits, ... and even if other, similar drugs offer the same benefits with less risk." *Bartlett*, 2010 WL 3303634, at *1, 2010 U.S. Dist. LEXIS 84924, at *4–5 (noting that the only exception would be drugs whose dosage or design could be altered to avoid the unreasonable danger).

document no. 332. Presumably, not every "prudent manufacturer" will choose to follow the same strategy.

Recognizing, apparently, that its withdrawal of the "comment k" defense undermines its position, Mutual argues in its Rule 59 motion that it withdrew the defense only because this court allegedly "confirmed" that doing so would render inadmissible any evidence regarding sulindac's warning, and that this court went back on that promise at trial, in violation of Mutual's due process rights. But that is not what happened. This court expressly reserved judgment on that evidentiary issue, both in its limine rulings, *see Bartlett*, 2010 WL 3092649, at *5 n. 5, 2010 U.S. Dist. LEXIS 111259, at *14–15, and at the final pretrial conference, during which Mutual first suggested that it might withdraw the defense (and another defense, known as "state of the art," *see* N.H. Rev. Stat. § 507:8–g), and Bartlett responded that warning-related evidence could be presented at trial anyway. *See* document no. 301, at 98–99; document no. 302, at 30–32, 52–54.

After the final pre-trial conference, this court expressly ordered that "[i]f Mutual withdraws the [state of the art] defense, then [its] procedures [for monitoring sulindac's risks] will no longer be relevant and thus will not be presented to the jury." *Bartlett v. Mut. Pharm. Co.*, 2010 WL 3219357, at *2 n. 5, 2010 U.S. Dist. LEXIS 92403, at *5 (document no. 329). This court never made any such statement with regard to the "comment k" defense and warning-related evidence. A few days before trial, Mutual informed the court during a conference call that it would decide "by the end of the day with regard to both [its] state of the art and unavoidably unsafe [defenses] whether

we're withdrawing those defenses so that what is left is only no label issues and only the issue about unreasonably dangerous." Document no. 353, at 37. This court replied with a one-word "understood," *id.*, and moved on to other pressing topics.

Mutual announced its withdrawal of both defenses later that day, *see* document no. 332, and Bartlett responded by immediately seeking a pre-trial ruling on the admissibility of warning-related evidence, *see* document no. 339. Mutual quickly filed two briefs arguing against the admission of such evidence, *see* documents no. 341, 342, and this court held another conference call with the parties devoted specifically to that issue. Not once did Mutual suggest, either in its briefs or during the conference call, that it believed this court (apparently by saying the word "understood" on the earlier conference call) had already promised to exclude warning-related evidence if Mutual withdrew its "comment k" defense. That fact alone belies Mutual's argument that it withdrew its "comment k" defense based on this court's ruling that doing so would eliminate any warning-related evidence from trial.

On the day before trial, this court ruled that warning-related evidence would be admissible, to a limited extent, with regard to the issue of whether sulindac was unreasonably dangerous. *See Bartlett*, 2010 WL 3303864, 2010 U.S. Dist. LEXIS 102603. Thus, while Mutual was indeed left with "only the issue about unreasonably dangerous" (to use its phrase from the earlier conference call), the warning still had some potential relevance to that issue. The first footnote of that same order explained that "Mutual recently withdrew its 'comment k' defense," and that "[u]ntil that defense was withdrawn, there was no

dispute that evidence of the warning's adequacy could be presented at trial, which is why this issue has not been resolved until now." *Id.*, 2010 WL 3303864, at *1 n. 1, 2010 U.S. Dist. LEXIS 102603, at *3–4 (citing *Bartlett*, 2010 WL 3092649, at *5 n. 5, 2010 U.S. Dist. LEXIS 111259, at *14–15).

Mutual never moved for reconsideration of that ruling, never disputed the order's account of the procedural history (until its Rule 59 motion), and even more importantly, never sought to reinstate its "comment k" defense on the ground that the withdrawal had been contingent on the exclusion of warning-related evidence (even throughout the trial, as Bartlett introduced the very evidence that Mutual now says it thought was inadmissible). Indeed, Mutual did not even ask this court to instruct the jury on the "comment k" defense. By failing to raise the issue in a timely manner, when this court easily could have afforded relief, Mutual waived its due process argument. *See, e.g., United States v. Carpenter*, 494 F.3d 13, 30 (1st Cir. 2007) ("the raise-or-waive rule ... precludes a party from making a tactical decision to refrain from objecting, and subsequently, should the case turn sour, assigning error," without having "afford[ed the trial court] an opportunity to correct the problem").

Even if Mutual's argument not been waived, it would be difficult for this court to view the argument as anything more than an unfounded, *post hoc* attempt to shirk responsibility for a voluntary strategic decision. Mutual has not shown any unfairness whatsoever relating to its withdrawal of the "comment k" defense, and certainly is not entitled to a new trial on that basis. Nor, in light of that withdrawal, is

Mutual entitled to judgment as a matter of law on the ground that sulindac is unavoidably unsafe, which (together with the adequacy of sulindac's warning) is an issue that Mutual itself chose to remove from the case.

iii. Safer alternative product

The next issue raised by Mutual's Rule 50 motion is whether Bartlett needed to present evidence of a safer alternative product (as opposed to a safer alternative design). Mutual argues that such proof is also required under New Hampshire law and that Bartlett failed to provide it. But Mutual has not cited, nor can this court find, any authority for such a requirement. *Cf. Heath v. Sears, Roebuck & Co.*, 123 N.H. 512, 530, 464 A.2d 288 (1983) (noting that "mere compliance with current industry practice" is not "a defense to [to defective design] liability" under New Hampshire law). Moreover, Mutual's argument is undermined by the fact that it objected—successfully—to this court's proposed instruction that the jury, in weighing sulindac's risks and benefits, could "consider whether there were alternative products on the market that provided the same benefits as sulindac, but with less risk."

Mutual argued, at the time, that the proposed instruction was inconsistent with a later instruction, included in the final jury charge, that "a manufacturer is not obliged to design the safest possible product, ... or one as safe as others make, so long as the design it has adopted is not unreasonably dangerous." Document no. 378, at 15–16 (quoting *Thibault*, 118 N.H. at 808, 395 A.2d 843). But there was no inconsistency: a jury can consider a factor without it

being dispositive.[27] That is clearly the role that a safer alternative design plays under New Hampshire case law, *see Vautour*, 147 N.H. at 156, 784 A.2d 1178 ("proof of an alternative design is ... neither a controlling factor nor an essential element"), and there is no reason to believe that a safer alternative product would be treated any differently.

While not required to do so, Bartlett presented considerable evidence for the jury to consider with regard to safer alternative products. *See* Part III.A.i, *supra*. For example, her experts testified that sulindac is part of two NSAID groups—acetic acid NSAIDs and longer half-life NSAIDs—believed to have a greater risk of SJS/TEN than other NSAIDs, with no greater benefits (aside from the "longer benefit" associated with having a longer half-life). In addition, they testified that aspirin and Tylenol, while perhaps not perfect alternatives to sulindac, have no risk of SJS/TEN, are equally effective in treating conditions like shoulder pain (for which Bartlett took sulindac), have additional benefits that sulindac does not have, and are safer alternative products overall.

Mutual argues that, to be considered a safer alternative, a product must be equally effective and less dangerous in all respects, not just overall. But in *Vautour*, where the plaintiffs' expert testified that "*under similar circumstances* [to those encountered by the plaintiff], machines with [an alternative] design would be, *overall*, less dangerous," the New Hampshire Supreme Court concluded that it "was up to the jury to assess the weight to be given this testimony." 147

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[27] Out of an abundance of caution, this court nevertheless granted Mutual's request to exclude the proposed instruction, allowing Bartlett to argue the point in her closing, but not instructing on it.

N.H. at 157, 784 A.2d 1178 (emphases added). Again, there is no reason to believe that safer alternative products would be treated any differently from safer alternative designs. So it was up to the jury, in assessing sulindac's risks and benefits, to determine how much weight (if any) to give Bartlett's evidence regarding safer alternative products.

iv. Causation

The next issue raised by Mutual's Rule 50 motion is whether Bartlett presented sufficient evidence of causation. *See, e.g., Vautour*, 147 N.H. at 154, 784 A.2d 1178 (requiring proof that the product's defective "condition caused injury to the user"). Mutual argues that Bartlett failed to do so, because she presented "no evidence whatsoever that any alternative design would have avoided [her] injury."[28] As already explained, however, the New Hampshire Supreme Court has expressly ruled that "the plaintiff is not required to present evidence of a safer alternative design." *Kelleher*, 152 N.H. at 831, 891 A.2d 477. By the same token, a plaintiff is not required to prove that the alternative design would have avoided her injuries.

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[28] Mutual also argues that this court's use of a general verdict form made it "impossible to determine if [the jury] concluded that plaintiff satisfied each element of a design defect claim," including causation. But the final jury charge made clear that "to recover on her claim for strict products liability, Mrs. Bartlett must prove each of the ... elements by a preponderance of the elements." Document no. 378, at 14. Given that instruction, there is no reason to doubt that the jury found Bartlett had proven each element. *See, e.g., United States v. Gentles*, 619 F.3d 75, 82 (1st Cir. 2010) ("It is a well established tenet of our judicial system that juries are presumed to follow [the court's] instructions."); *Goulet v. New Penn Motor Express, Inc.*, 512 F.3d 34, 43 n. 6 (1st Cir. 2008) (finding no fault with the use of general verdict form where "the jury was amply instructed" on the requirements for liability).

See Vautour, 147 N.H. at 153, 784 A.2d 1178 (ruling that plaintiffs presented trialworthy claim even though their "expert failed to offer any testimony regarding ... how his proposed alternative design would prevent the type of injuries suffered").

Mutual also argues that, since this court allowed the jury to consider whether sulindac's warning avoided an otherwise unreasonable danger, *see Bartlett*, 2010 WL 3303864, at *4, 2010 U.S. Dist. LEXIS 102603, at *11 (citing *Vautour*, 147 N.H. at 154, 784 A.2d 1178), there was no causation because Bartlett's doctor never read that warning.[29] But Mutual never "distinctly articulated" that argument in its close-of-evidence motion for a directed verdict under Rule 50(a), so it cannot be raised now. *Parker v. Gerrish*, 547 F.3d 1, 12 (1st Cir. 2008) (explaining that a Rule 50(b) motion "is bounded by the movant's earlier Rule 50(a) motion"). Indeed, this court cannot find *any* warning-related arguments that Mutual "distinctly articulated" in its Rule 50(a) motion and then renewed in its Rule 50(b) motion.[30] So for Rule 50 purposes, at least, sulindac's warning is no longer at issue.

Moreover, even if properly raised, Mutual's warning-related causation argument would fail on the merits. The warning was not sulindac's defective condition; the unreasonable danger was. *See* document no. 378, at 16 (instructing the jury that it could consider the warning only if it determined, first, that

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[29] As discussed *supra*, that was why this court granted summary judgment to Mutual on Bartlett's failure-to-warn theory. *See Bartlett*, 731 F. Supp. 2d at 145–49.

[30] *See* Part III.B.iii, *infra* (discussing Mutual's warning-related pre-emption argument, which was raised in the Rule 50(a) motion but not again until the Rule 50(b) reply).

sulindac was unreasonably dangerous, and even then, only to determine whether the warning avoided the unreasonable danger); *Bartlett*, 2010 WL 3303864, 2010 U.S. Dist. LEXIS 102603. The fact that Bartlett's doctor never read a warning that, in the jury's view, did not eliminate sulindac's unreasonable danger, was of no consequence. The chain of causation on a defective design claim does not run through the warning. *See, e.g., Vautour*, 147 N.H. at 154, 784 A.2d 1178 (requiring only proof that the defective "condition caused injury to the user").

Mutual argues, finally, that "unreasonable danger does not cause an injury." Again, however, Mutual never "distinctly articulated" that argument in its Rule 50(a) motion, so it cannot be raised now under Rule 50(b). *Parker*, 547 F.3d at 12. Moreover, even if properly raised, the argument would fail on the merits. What made sulindac unreasonably dangerous, according to Bartlett, was "its inherent propensity to cause SJS/TEN." That was the (sole) theory that Bartlett presented to the jury, both in her opening statement and her closing argument (using the quoted language both times).[31] The evidence was overwhelming, and essentially uncontested, that Bartlett suffered SJS/TEN as a side effect of sulindac. So there was sufficient evidence for the jury to find causation.

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[31] Mutual protests that this court never instructed the jury on that theory. But Bartlett sought such an instruction in the final jury charge, and Mutual successfully opposed it, persuading this court that it might be misconstrued as implicitly endorsing the theory.

B. *Federal pre-emption*

The other issue raised by Mutual's Rule 50 motion, in addition to the sufficiency of the evidence, is federal preemption. "A fundamental tenet of our federalist system is that constitutionally enacted federal law is supreme to state law. *See* U.S. Const. art. VI cl. 2. As a result, federal law sometimes pre-empts state law either expressly or by implication." *N.H. Motor Transp. Ass'n v. Rowe*, 448 F.3d 66, 74 (1st Cir. 2006), *aff'd*, 552 U.S. 364, 128 S. Ct. 989, 169 L.Ed.2d 933 (2008). Federal "preemption is an affirmative defense upon which [the] defendant bears the burden of proof." *Cambridge Literary Props., Ltd. v. W. Goebel Porzellanfabrik G.m.b.H. & Co.*, 510 F.3d 77, 102 (1st Cir. 2007); *see also Wyeth*, 129 S. Ct. at 1193 (characterizing a manufacturer's argument that federal drug law pre-empted the plaintiff's claims as a defense). Here, Mutual has made essentially four different pre-emption arguments. This court will address each of them in turn.

i. "Second-guessing" the FDA

First, Mutual argues that federal law (specifically, the FDCA and related FDA regulations) impliedly pre-empts any state-law tort claim that requires the jury to "second-guess" the FDA's risk/benefit analysis of a drug, because such claims "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[32] *Good v. Altria Group, Inc.*, 501 F.3d 29, 47 (1st Cir. 2007), *aff'd*, 555 U.S. 70, 129 S. Ct. 538, 172 L.Ed.2d 398 (2008) (describing the

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[32] It is worth noting that Mutual did not raise this preemption argument in its earlier motions for judgment on the pleadings or for summary judgment, which raised the other preemption arguments discussed *infra*.

doctrine of obstacle pre-emption). As support for that argument, Mutual relies on *Geier v. American Honda Motor Co.*, 529 U.S. 861, 120 S. Ct. 1913, 146 L.Ed.2d 914 (2000), where the Supreme Court held that a federal regulation that called for a gradual phase-in of airbags in cars pre-empted state-law tort claims based on a manufacturer's failure to install airbags earlier, because such claims presented an obstacle to achieving Congress's objectives, which included winning consumer acceptance of airbags and spurring further technological innovation during the phase-in period.

This case, however, has very little (if anything) in common with *Geier*. It has much more in common with *Wyeth*, 129 S. Ct. at 1187, a more recent case where a drug manufacturer argued—much like Mutual does here—that "because the FDCA requires the FDA to determine that a drug is safe and effective under the conditions set forth in its labeling, the agency must be presumed to have performed a precise balancing of risks and benefits and to have established a specific labeling standard that leaves no room for different state-law judgments." *Id.* at 1200. The Supreme Court rejected that argument, concluding that the regulatory framework applicable to prescription drugs is "quite different" from the one in *Geier* and that "the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 1202–03.

Wyeth is arguably not directly controlling here, because it involved a failure-to-warn claim, not a defective design claim. But this court cannot see, nor has Mutual articulated, any reason why *Wyeth's* logic would not extend to this closely analogous context. *Cf. Wimbush v. Wyeth*, 619 F.3d 632, 645 (6th Cir. 2010)

(concluding that *Wyeth's* "rationale extends beyond the realm of failure-to-warn claims to apply to all pre-approval state law claims," including, in that case, a claim of negligence in bringing an FDA-approved drug to the market). Mutual has not cited any cases, before or since *Wyeth*, that interpreted federal law as prohibiting juries from deeming an FDA-approved drug to be more risky than beneficial. *See Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 537 (6th Cir.), *cert. denied*, 510 U.S. 914, 114 S. Ct. 304, 126 L.Ed.2d 252 (1993) ("reject[ing] the argument that FDA approval pre-empts state product liability claims based on design defect," and noting that the "great majority" of courts had done the same[33]). Mutual's pre-emption argument is therefore rejected.

Relatedly, Mutual argues in its Rule 59 motion that this court violated due process by allowing Bartlett to "attack" the FDA's decision to approve sulindac, thereby "putting the FDA on trial" even though it was not a party to the case and even though "plaintiff's claims were not related to FDA or its actions related to sulindac." But even assuming, *dubitante*, that Mutual

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[33] *Tobin*, incidentally, belies Mutual's repeated refrain that this case is unprecedented in holding a drug manufacture liable for defective design under a risk/benefit analysis. In that case, which involved injuries caused by the drug ritodrine, the Sixth Circuit agreed with the manufacturer that (as here) the plaintiff could not recover on her failure-to-warn theory due to a lack of causation, *id.* at 536, but nevertheless upheld a jury verdict of liability on a defective design theory, where (as here) "evidence of the risks and benefits associated with ritodrine were a main focus" at trial, *id.*, and the plaintiff's theory was that the drug posed a risk of "disturbing" side effects, *id.* at 539, with only "some benefit," *id.* at 537 n. 8. The Sixth Circuit ruled that there was sufficient evidence for the jury to disagree with the FDA's risk/benefit analysis. *Id.* at 538.

has standing to raise the due process rights of a non-party, that argument clearly has no merit. The FDA's "actions related to sulindac" were quite relevant to Bartlett's claim. *See* Fed. R. Evid. 401 (evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence ... more or less probable"). Indeed, Mutual repeatedly emphasized the FDA's approval of sulindac throughout the trial. If anything, it would have violated Bartlett's due process rights to allow Mutual to use the FDA's approval as a shield to liability, without allowing Bartlett to challenge it.

ii. Design pre-emption for generic drugs

Second, Mutual argues that federal law (again, the FDCA and related FDA regulations) prohibited manufacturers from unilaterally changing the design of a generic drug, thus making "compliance with both state and federal law ... impossible." *Good*, 501 F.3d at 47 (describing the doctrine of impossibility pre-emption). As already explained, however, Mutual was not held liable for failing to change sulindac's design; it was held liable for selling an unreasonably dangerous product, with greater risks than benefits. Federal law did not require Mutual to sell sulindac. Nor, for that matter, did state law require Mutual to stop selling it, or to redesign it. *See Bartlett*, 2010 WL 3092649, at *8, 2010 U.S. Dist. LEXIS 111259, at *24 ("what strict products liability requires is that manufacturers compensate consumers for the damage caused by unreasonably dangerous products, not necessarily that they remove such products from the market" or "retrofit" them) (citing 5 Frumer & Friedman, *supra*, § 57.01[4], at 57–9). So it was not "impossible" for Mutual to comply with both federal and state law. *Cf.*

Barnett Bank of Marion County, N.A. v. Nelson, 517 U.S. 25, 31, 116 S. Ct. 1103, 134 L.Ed.2d 237 (1996) (explaining that impossibility pre-emption arises "if the federal law said, 'you must sell insurance,' while the state law said, 'you may not' ").

iii. Warning pre-emption for generic drugs

Third, Mutual attempts in its reply brief on its Rule 50 motion to raise the pre-emption argument that it advanced unsuccessfully earlier in this case: that federal law (again, the FDCA and related FDA regulations) prohibited manufacturers from unilaterally changing the warning for a generic drug, thus making it impossible for Mutual to comply with both federal and state law. *See Bartlett*, 659 F. Supp. 2d at 279 (concluding that federal law allowed such changes and therefore did not pre-empt Bartlett's claims); *accord Demahy*, 593 F.3d at 428; *Mensing*, 588 F.3d at 603. Mutual failed, however, to raise that warning-related pre-emption argument in its opening brief in support of either of its post-trial motions. The argument is therefore waived. *See, e.g., Doe v. Friendfinder Network, Inc.*, 540 F. Supp. 2d 288, 303 n. 16 (D.N.H. 2008); L.R. 7.1(e)(1) (reply is "restricted to rebuttal of factual and legal arguments raised in the objection").[34]

The argument is also moot, since this court granted summary judgment to Mutual on Bartlett's failure-to-

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[34] The same is true of Mutual's argument that this court erred by failing to instruct the jury that Mutual could not change its warning, which also appeared for the first time in the reply brief. Moreover, such an instruction would have been inconsistent with the instruction set forth in the next paragraph, *infra*, which is presumably why Mutual did not object to the final jury charge on that basis.

warn theory, *see Bartlett*, 731 F. Supp. 2d at 145–48, and Mutual withdrew its "comment k" defense, *see* document no. 332, thereby eliminating from the case the issue of whether Mutual could have or should have strengthened sulindac's warning. Indeed, this court expressly instructed the jury (at Mutual's request) that Mutual's "conduct in ... responding" to sulindac's safety risks, which included any failure to change its warning, was "not relevant to this case, and you should put [it] out of your mind." *See* document no. 378, at 22.[35] Mutual protests that the warning was still a part of the case, which is true, but not in the sense that Mutual could have been held liable for failing to change it. *See Bartlett*, 2010 WL 3303864, at *1, 2010 U.S. Dist. LEXIS 102603, at *4 (Bartlett "must prove that sulindac was unreasonably dangerous *despite* its warning, not *because* of it.").

Moreover, even if it were neither waived nor moot, this court would reject Mutual's argument on the merits, for the reasons explained at length in its earlier opinion. *See Bartlett*, 659 F. Supp. 2d at 279. Mutual argues that a recent amicus brief filed by the United States Solicitor General in *Mensing* calls this court's reasoning into question. *See* Brief of the United States as Amicus Curiae, 2010 WL 4339894, at *13, *Pliva*,

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[35] As this court explained in a previous ruling, strict liability "claims focus on the product itself rather than the defendant's conduct." *Bartlett*, 2010 WL 3659789, at *12, 2010 U.S. Dist. LEXIS 96711, at *38 (citing 2 Frumer & Friedman, *supra*, § 14.03[1][b], at 14–35, and *Racer v. Utterman*, 629 S.W.2d 387, 395 (Mo. App. Ct. 1981), which noted that "most ... courts have treated strict liability in tort as a doctrine which looks to the product not to the conduct of the manufacturer" and that "liability arises because of the condition of the product regardless of the care exercised by the manufacturer").

Inc. v. Mensing, No. 09–993 (U.S. Nov. 2, 2010) (stating, albeit with limited discussion, that the manufacturer of a generic drug "may not unilaterally change its approved labeling"). But the Solicitor General's view is not dispositive. *See Wyeth*, 129 S. Ct. at 1201–04 (disagreeing with Solicitor General's view on a similar issue). This court still finds the reasoning in its earlier opinion—and later adopted in *Demahy*, 593 F.3d at 440—to be more persuasive.

iv. *Buckman* pre-emption

Finally, in what amounts to a fourth pre-emption argument, Mutual argues in its Rule 59 motion that this court erred by allowing the jury, in determining whether sulindac's warning avoided an otherwise unreasonable danger, to consider whether the warning complied with FDA labeling requirements, because only the federal government has authority to enforce those requirements. *See* 21 U.S.C. § 337(a) (all such proceedings for the enforcement [of the FDCA] "shall be by and in the name of the United States"). As support for that proposition, Mutual relies on *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S. Ct. 1012, 148 L.Ed.2d 854 (2001), where the Supreme Court held that state-law claims for fraud-on-the-FDA were impliedly pre-empted by the FDCA, in part because they would interfere with the FDA's statutory power to enforce its own disclosure requirements. *Id.* at 349, 121 S. Ct. 1012.

Buckman pre-emption, however, applies where a state-law claim arises "solely from the violation of FDCA requirements." *Id.* at 352–53, 121 S. Ct. 1012. That is not even close to the situation here. This court instructed the jury that "compliance or non-compliance with FDA labeling requirements is not necessarily

conclusive or controlling" on the issue of whether sulindac's warning avoided an otherwise unreasonable danger, and could be given "as much or as little weight as you think it deserves, in light of all the evidence." Document no. 378, at 19. Moreover, this court instructed the jury that it could not even consider sulindac's warning and the FDA requirements unless it determined, first, that sulindac was unreasonably dangerous. *Id.* at 16, 19. So Bartlett's claim did not arise from a violation of FDA requirements at all (much less "solely"); it arose from sulindac's unreasonable danger.

Mutual has not cited any authority for extending *Buckman* pre-emption to this very different context. Indeed, there is a split of authority regarding whether *Buckman* pre-emption even extends to negligence claims where FDA regulations establish a *per se* standard of care. *See Bartlett*, 731 F. Supp. 2d at 154–56 (citing cases on both sides of that issue). This case is far removed even from that. Moreover, even assuming *dubitante* that this court erred by instructing the jury on the FDA's labeling requirements, Mutual has not shown that doing so was "tantamount to a miscarriage of justice." *Crowe*, 506 F.3d at 19. Mutual made the FDA's approval of sulindac's warning a point of emphasis throughout the trial. It was not unjust for the jury to be told what the FDA's standards for approval were and to be able to consider them in evaluating the warning.[36]

C. *Judicial conduct*

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[36] Mutual has not made any Rule 50 argument for *Buckman* preemption, either at the close of evidence or post-trial, so to that extent the argument is waived. *See Parker*, 547 F.3d at 12.

Having determined that Bartlett presented sufficient evidence to support her claim and that the claim is not preempted by federal law, this court will now turn to the remaining issues raised by Mutual's Rule 59 motion. The first such issue relates to this court's conduct. Mutual argues that a new trial is necessary because "the proceedings were not being conducted in an impartial fashion," but rather in such a way as to favor Bartlett and disfavor Mutual. As support for that argument, Mutual points to a handful of comments and actions by this court that, in its view, suggest judicial bias. As explained below, however, Mutual has taken those comments and actions out of context, or otherwise misconstrued them. This court sincerely meant what it said in the final jury charge: that it "is neutral and impartial in this matter and does not take sides." Document no. 378, at 32.

It is important, in considering Mutual's specific allegations of bias, to keep in mind the bigger picture. *See, e.g., United States v. DeCologero,* 530 F.3d 36, 56 (1st Cir. 2008) ("Charges of partiality should be judged not on an isolated comment or two, but on the record as a whole."). This is a case where the court granted summary judgment to Mutual on nearly all of Bartlett's claims, one of them *sua sponte. See Bartlett,* 731 F. Supp. 2d 135; *Bartlett,* 2010 WL 3659789, 2010 U.S. Dist. LEXIS 96711. Moreover, this court kept a tight rein on Bartlett's counsel throughout the trial, as described in Part D, *infra.* It is understandable, then, that Bartlett's counsel regard Mutual's judicial bias argument as "totally contrary to the plaintiff's experience during the entirety of this case including every minute of trial." Document no. 409–1, at 4.

Moreover, it should be noted that Mutual's purported examples of judicial bias—culled from a nearly three-year litigation requiring hundreds of pre-trial rulings, and culminating in a three-week trial—come nowhere near the kind of conduct that our court of appeals has deemed *insufficient* to demonstrate judicial bias or require a new trial. *See United States v. Rodriguez-Rivera*, 473 F.3d 21, 28 (1st Cir. 2007) (collecting cases where "stern [ ] rebukes of counsel or litigants [were] insufficient to demonstrate judicial bias," including trial judges' calling plaintiff "an absolute and incorrigible liar," referring to defense counsel's cross-examination as "very devious," and warning counsel he was being reported for violating the rules of professional conduct).

i. Ruling on motion before sur-reply

First, Mutual points to a ruling that this court made on a motion to strike filed by Bartlett, before Mutual had filed its sur-reply.[37] The motion sought to strike Mutual's expert Dr. Stern for failing to produce the Pharmacia report (discussed in Part III.A.i, *supra*). After reviewing Bartlett's motion, Mutual's objection, and Bartlett's reply, this court granted the motion in part. *See* document no. 251. While not striking Dr. Stern altogether, this court agreed with Bartlett that the report should have been disclosed earlier and, given its potential significance, ordered that Dr. Stern (and one other defense expert) be made available for supplemental depositions regarding the report. At that

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[37] To the extent that Mutual refers to other unidentified "motions," its argument is conclusory and insufficiently developed.

point, only one month remained until trial, so time was of the essence.

Shortly after this court's order, Mutual sought leave to file a sur-reply. While not required to accept a sur-reply on a non-dispositive motion, *see* L.R. 7.1(e)(3) ("leave to file a surreply will only be granted under extraordinary circumstances"), this court nevertheless granted Mutual's request and then issued another order—longer than the first—analyzing and rejecting the arguments raised in Mutual's sur-reply. *See Bartlett v. Mut. Pharm. Co.*, 2010 WL 2990824 (document no. 272). This court gave the sur-reply full consideration, and did so with an open mind. Mutual may have disliked the result, but neither the result nor the process leading up to it reflects judicial bias. *See also, e.g., Bartlett*, 2010 WL 3303634, 2010 U.S. Dist. LEXIS 84924 (giving full consideration to Mutual's motion to reconsider the denial of an earlier motion to reconsider).

ii. Comments during discovery hearing

Next, Mutual points to this court's statement, made during a discovery-related hearing in October 2009, that Mutual is a "giant corporation" represented by "experienced counsel" from a "huge law firm." It is important to put those statements in their proper context. The issue before the court during that hearing was whether to sanction Mutual under Fed. R. Civ. P. 37(c)(1) for failing to timely produce certain FDA filings that Bartlett had specifically requested in discovery. *See Bartlett v. Mut. Pharm. Co.*, 2009 DNH 166, 2009 WL 3614987, 2009 U.S. Dist. LEXIS 102494 (imposing some, but not all, of the sanctions Bartlett sought); *but see* document no. 125 (disallowing the

monetary part of the sanctions after Bartlett failed to timely submit an itemized bill).

Mutual, as part of its argument against sanctions, alleged that Bartlett, too, had failed to produce certain documents kept in her home, but explained that Mutual had declined to seek sanctions on that basis, considering it unprofessional. This court responded that "your point is well taken," but noted that the analysis of whether a discovery error is substantially justified under Rule 37(c)(1) might be "a little bit different" for "Mutual with its ... experienced counsel with 20 years experience in this type of litigation" than for "a plaintiff who is disabled and has probably never been ... in a litigation before." This court went on to clarify:

I'm not going to hold [Bartlett] to a different standard than you. That's not what I mean to say. You probably get sick of hearing that you're the giant corporation with the huge law firm, but you deal with this every day, and to me there's a difference between dropping the ball on this discovery request and a plaintiff who left some [documents in her house]."

Document no. 99, at 46–47.

As that context makes clear, this court was not denigrating Mutual as a "giant corporation with [a] huge law firm;" to the contrary, it was acknowledging that such characterizations can be tiresome. Nevertheless, this court was expressing skepticism about Mutual's suggested analogy between its failure to produce its FDA filings, which "are standard fare for discovery in pharmaceutical litigation of this sort," *Bartlett*, 2009 WL 3614987, at *4, 2009 U.S. Dist. LEXIS 102494, at *12, and Bartlett's failure, as a blind plaintiff, to locate certain documents in her home and

produce them. Whatever one may think of that analogy and this court's response to it, neither had any bearing on the sanctions ruling (which was based on Mutual's discovery error, not how it compared with Bartlett's alleged error) or any other ruling in this case.

iii. Comments during trial conference

Next, Mutual points to this court's comment, made during a trial conference conducted outside the presence of the jury, that "I want you to prove your case if you can." Mutual interprets that statement to mean that this court wanted Bartlett to prevail on the merits. But that is not at all what the court was saying, as the context again makes clear. The court was in the process of explaining to Bartlett that one of the opinions given by her expert Dr. Tackett (regarding sulindac's risk of liver toxicity) had not been properly disclosed in his expert report and that the court would be instructing the jury to disregard that testimony. In other words, the court was in the process of granting relief requested by Mutual.

Before granting that relief, this court asked Bartlett if she could identify "anything remotely representing [a disclosure of Dr. Tackett's opinion] to try to give you the benefit of the doubt because you are the plaintiff and I want you to prove your case if you can—I want you to be able to prove your case without barriers from me." This court did not mean, by that statement, that it wanted Bartlett to prevail over Mutual in the end. Rather, this court meant only that it wanted Bartlett to be able to present her case without any artificial barriers from the court—provided she stayed within the confines of the Federal Rules of Evidence and Civil Procedure. Perhaps, in retrospect, the point could

have been better worded, but it was not reflective of judicial bias.

iv. "Smoking gun"

Next, Mutual complains that this court, outside the presence of the jury, referred to the Pharmacia report as a "smoking gun." That was how Bartlett referred to the report in her filings. *See* document no. 230–1, at 6 ("This document, quite literally, is the smoking gun of smoking guns."). This court did not agree with that over-the-top characterization; to the contrary, it told the parties early in the trial that "I am much less inclined to think that [the report] has anything approaching the smoking gun." Nevertheless, this court used the phrase "smoking gun," or "so-called smoking gun," as a shorthand that the parties would instantly recognize. The jury never heard that phrase, so it obviously had no affect on the trial or the verdict. Nor did its use reflect judicial bias.

v. Rephrasing questions

Next, Mutual points to a few occasions during trial when this court rephrased questions by Bartlett's counsel that were leading or lacking in foundation. But this court did not intervene on those occasions out of favor for Bartlett; it did so to fulfill its responsibility to "exercise reasonable control over the mode ... of interrogating witnesses and presenting evidence so as to (1) make the interrogation and presentation effective for the ascertainment of the truth," and "(2) avoid needless consumption of time." Fed. R. Evid. 611(a); *see also Nat'l R.R. Passenger Corp. v. Certain Temporary Easements*, 357 F.3d 36, 42 (1st Cir. 2004) ("Decisions regarding the mode ... of witness questioning lie within the district court's broad discretion").

Contrary to what Mutual suggests, this court's involvement in questioning was quite minimal; it did not "advantage or disadvantage a party unfairly," or indeed at all. *United States v. Angulo–Hernandez*, 565 F.3d 2, 10 (1st Cir. 2009) (concluding that even a "court's rather frequent questioning and commentary" did not cross the line, where the court's intent was "to clarify testimony, respond to defense counsels' objections, ... and expedite the trial, all legitimate purposes"); *cf. also Rodriguez–Rivera*, 473 F.3d at 27–28 (similar); *Raviart v. Yates*, No. 03–0164, 2007 WL 2505575, *14, 2007 U.S. Dist. LEXIS 64712, at *38 (E.D. Cal. Aug. 31, 2007) (concluding that "the trial judge's involvement in the questioning of witnesses did not bespeak a bias in favor of the prosecution or otherwise render petitioner's trial fundamentally unfair").

vi. Blowing nose and wiping eyes

Finally, Mutual argues that this court gave at least an appearance of partiality by blowing its nose and wiping its eyes during some emotional testimony by Bartlett's sister. But this court specifically addressed that issue with the jury (after Mutual raised concerns the next morning), explaining that "as a matter of fact I did not have an emotional reaction to that testimony. I was merely blowing my nose and dealing with a little allergic, itchy eye." Many of the jurors nodded in understanding. This court further instructed the jury that even if someone observing the trial were to have an emotional reaction to the evidence presented, it would not have "any bearing upon this case" and "wouldn't be something you should consider one way or the other." Those frank instructions cured any possible prejudice to Mutual. *See, e.g., Rodriguez–Rivera*, 473

F.3d at 28–29 ("such a charge usually mitigates any perceived partiality from the bench").

D. *Counsel's conduct*

The next issue raised by Mutual's Rule 59 motion relates to the conduct of Bartlett's counsel. Mutual argues that a new trial is necessary because, from voir dire to closing argument, Bartlett's counsel "engaged in conduct designed to improperly inflame and influence the jury." In determining whether allegedly improper conduct by counsel warrants a new trial, "the court must examine the totality of the circumstances, including (1) the nature of the comments; (2) their frequency; (3) their possible relevance to the real issues before the jury; (4) the manner in which the parties and the court treated the comments," including any curative instructions; "(5) the strength of the case; and (6) the verdict itself." *Granfield v. CSX Transp., Inc.*, 597 F.3d 474, 490 (1st Cir. 2010).

As explained below, there is no question that Bartlett's counsel made this court's job at trial more difficult than it needed to be, repeatedly testing the limits of this court's rulings (not to mention its patience). Anticipating just such an approach, however, this court kept a tight rein on Bartlett's counsel throughout the trial, imposing various restrictions to prevent misconduct, stopping counsel whenever they pushed too far (sometimes in response to Mutual's objections, but often *sua sponte*), giving curative instructions or other relief where appropriate (again, often *sua sponte*), and even reprimanding counsel in front of the jury a few times. As a result, whether or not counsel's conduct was "designed to improperly inflame and influence the jury," this court is confident that it did not have that effect.

i. Voir dire

First, Mutual argues that Bartlett's counsel improperly asked prospective jurors, during attorney-conducted voir dire, whether they would be unable to award damages greater than $20 million. But this court sustained Mutual's objection to that question and prohibited Bartlett's counsel from using specific dollar figures from that point forward. Bartlett had expressly disclosed before trial that she intended to ask such questions and, indeed, argued that she was entitled to do so. *See* document no. 259, at 3 (citing *Geehan v. Monahan*, 382 F.2d 111, 115 (7th Cir. 1967)). So if Mutual wanted to prevent the questions from being asked at all, it should have filed a specific objection before trial, rather than merely objecting in general to Bartlett's request for attorney-conducted voir dire, and then waiting to object to specific questions after they had already been asked.

In any event, this court is not persuaded that the limited questioning about a specific damage figure caused any prejudice to Mutual, especially in light of this court's immediate intercession.[38] This court expressly instructed the jury, in the final charge, that any amount mentioned by Bartlett's counsel was "not evidence in this case" and that any damage award needed to be "based solely on the evidence presented

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[38] Indeed, there is a split of authority on whether such questioning is even improper in the first place. *See* Richard L. Ruth, *Propriety of inquiry on voir dire as to juror's attitude toward amount of damage awards*, 63 A.L.R.5th 285, §§ 2[a] and 3[a] (1998) (noting that "several courts have established as a general rule that a party may inquire on voir dire as to prospective jurors' attitudes toward specific damage figures," though some courts have disagreed, as this court did by sustaining Mutual's objection).

during the course of the trial." Document no. 378 at 28.[39] As explained in Part III.F, *supra*, this court has no reason to believe that the jury ignored that instruction.

ii. Demonstrative aids

Next, Mutual argues that Bartlett's counsel misused two demonstrative aids: a visual presenter known as an "Elmo," on which Bartlett's counsel allegedly left exhibits for longer than necessary, and an easel, on which Bartlett allegedly summarized evidence in a misleading fashion. But this court, after noticing some initial misuse of those aids, severely restricted Bartlett's counsel in the use of both (in addition to correcting, by way of a contemporaneous instruction, the misleading information on the easel). Specifically, this court restricted Bartlett's counsel to publishing exhibits on the Elmo only while asking the witness a question to which the exhibit related. And this court prohibited Bartlett's counsel from referring back to the easel during closing argument. Those restrictions prevented any possible prejudice to Mutual.

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[39] During an in-chambers conference before the final jury charge, Bartlett's counsel disclosed that they also planned to request a specific amount in closing (which turned out to be "between $20 and $30 million"). The parties agreed to the instruction set forth above as a means of addressing that request. Mutual did not object to the request then, or when it happened, and has not raised it as an issue in its Rule 59 motion. In light of that, it is nearly impossible to imagine that Mutual could have been prejudiced by counsel's mentioning the $20 million figure during jury selection.

iii. Staging dramatic moments

Next, Mutual argues that Bartlett's counsel improperly staged two dramatic moments designed to elicit sympathy from the jury: (1) having Bartlett return late to the courtroom after one break in testimony, with the hope that the jury would see her walk, with assistance, to counsel's table; and (2) having Bartlett's husband Greg sob in view of the jury while Bartlett's sister was testifying, and then leave the gallery. But the first moment never happened. Mutual brought Bartlett's absence to this court's attention, the jury was briefly excused (without being told why), and Bartlett returned to the courtroom before the jury did, so that the jury never saw her walking (except when she walked to and from the witness stand). So that incident had no effect on the jury whatsoever.

As for the sobbing by Bartlett's husband, this court cannot recall it (or any objection by Mutual, which would have made a record of it), but takes Mutual at its word that it did. Indeed, one can hardly be surprised that a husband would cry at some point during a three-week trial relating to severe injuries suffered by his wife. Most courts have concluded, however, that a brief emotional reaction of that sort does not warrant a new trial, "at least if the judge admonished the jury to disregard such manifestation in reaching their verdict." L.S. Tellier, *Manifestation of emotion by party during civil trial as ground for new trial*, 69 A.L.R.2d 954, § 2 (1960); *see also, e.g.*, *Malandris v. Merrill Lynch*, 703 F.2d 1152, 1179 (10th Cir. 1981). This court gave precisely such an

instruction on the day following Bartlett's sister's testimony, as discussed in Part III.C.vi, *supra*.[40]

iv. Net sales figure

Next, Mutual argues that Bartlett's counsel improperly allowed the jury to see Mutual's annual net sales figure during videotaped testimony by Mutual employee Robert Dettery.[41] This court ruled before trial that Bartlett could not present any evidence of Mutual's financial condition, *see Bartlett*, 2010 WL 3092649, at *8, 2010 U.S. Dist. LEXIS 111259, at *25–27 (explaining that such evidence was not relevant), and specifically ruled that Bartlett could not show the jury the following question-and-answer from Dettery's videotaped testimony: "Q. And '07 sales were greater than $480 million? A. I'm not sure." Document no. 352, at 5. Bartlett's counsel modified the video presentation so that those words were not audible, but the question (without the answer) nevertheless appeared briefly in the subtitles, before the video and subtitles jumped ahead to the next admissible question-and-answer.

The parties disagree about whether that error was intentional. At trial, Bartlett's counsel told this court that it was a computer glitch, resulting from the way that their software program synched up the

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[40] Mutual also complains that Bartlett's husband violated this court's witness sequestration order by observing part of his sister-in-law's testimony. *See Bartlett*, 2010 WL 3092649, at *9, 2010 U.S. Dist. LEXIS 111259, at *28–29 (citing Fed. R. Evid. 615). But Bartlett's husband never testified at trial, so sequestration was not necessary.

[41] Mutual moved for a mistrial on that basis shortly after Dettery's testimony. *See* document no. 358. This court heard argument on the motion and then denied it orally.

video/audio file and the separate text file shown in the subtitles. They attempted to replicate the glitch for this court a number of times, but were unable to do so. Mutual, with the support of an affidavit from the managing director of the software company that made the program, claims that a glitch of that sort is impossible and therefore must have been a deliberate act (if not a criminal one). Bartlett's counsel, in turn, claim that they have now replicated the glitch, having figured out through discussions with the software company that it resulted from the difference in screen-size ratios between their laptop computer and the court's televisions.

This court need not resolve that debate, however, because—even if intentional—the brief, silent display of a question containing Mutual's net sales figure still would not warrant a new trial. The jury already knew, from Mutual's own statement during voir dire, that Mutual had 500 employees (which itself elicited a note of caution from this court, since Mutual's statement came close to implying to the jurors that employee jobs might be at stake, making it potentially prejudicial to Bartlett). And the jury knew, from Dettery's admissible testimony, that Mutual had a portfolio of about 250 generic drugs, as well as a few brand-name drugs. So with or without seeing the net sales figure, the jury surely assumed that Mutual had substantial annual sales. *See, e.g., Simek v. J.P. King Auction Co.*, 160 Fed. Appx. 675, 685 (10th Cir. 2005) (unpublished) (finding no prejudice from question about net worth where the "evidence already tended to show [the party's] wealth").

Moreover, this court expressly instructed the jury that " [q]uestions ... by lawyers are not evidence,

unless the witness adopts the facts set forth in the question," and that "[t]estimony that has been excluded ... is not evidence and must not be considered." Document no. 378, at 9–10. To the extent that the jurors even noticed the net sales figure (which is unknown), they surely also noticed that it was contained in a question that was neither spoken aloud nor answered by the witness, indicating that, pursuant to this court's instructions, it was not evidence and could not be considered. Under the totality of the circumstances, this court does not believe that Mutual suffered any significant prejudice from the brief, silent display of the annual sales question.[42]

v. Expert's "script" or "notes"

Next, Mutual argues that Bartlett's counsel improperly prepared a document (Mutual calls it a "script," Bartlett calls it "notes") for one of Bartlett's experts, Dr. Tackett, to use during his testimony. *See* document no. 394–1. The document contained hundreds of typed questions, some with handwritten answers next to them and/or citations to expert reliance materials. The document also contained about a dozen points for Dr. Tackett to make during cross-examination. Dr. Tackett testified at trial that Bartlett's counsel typed up the document based on their telephone conversations before trial and gave it to

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[42] This case is nothing like the one on which Mutual relies, *City of Cleveland v. Peter Kiewit Sons' Co.*, 624 F.2d 749 (6th Cir. 1980), where counsel "almost continuously sought to plant the seed in the minds of the jurors that [defendant] was a very large corporation with international operations" and "to inject into the trial the idea that [defendant] had insurance which would cover any damages." *Id.* at 756–58. Bartlett's counsel did not invoke Mutual's financial condition at all, much less "continuously," after the silent display of the sales figure.

him the day before his testimony. Mutual noticed the document during Dr. Tackett's direct examination and used it to challenge his credibility on cross-examination, asking detailed questions about how the document was prepared and how Dr. Tackett had used it. Indeed, that was Mutual's opening salvo on both days of Dr. Tackett's cross-examination.

While Bartlett claims that it is "common witness preparation" to discuss questions and answers with expert witnesses before their testimony, and sometimes even to write them out in a "script," *LeCroy v. Sec'y, Fla. Dep't of Corr.*, 421 F.3d 1237, 1267 (11th Cir. 2005) it is a strange practice, if not an improper one, for the witness to carry such a document with him to the stand and refer to it while testifying. Indeed, it is rather like walking into a punch, given how bad it looks to the jury on cross-examination. This court is not persuaded, however, that the document resulted in Dr. Tackett's giving opinions that were not his own, or that were not reliably based on his knowledge and expertise.[43] Nor is this court persuaded that the document's use caused any prejudice to Mutual, especially in light of Mutual's effective cross-examination of Dr. Tackett, based on the "script" itself.

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[43] This case is nothing like the one on which Mutual relies, *In re Scrap Metal Antitrust Litig.*, No. 02–cv–0844, 2006 WL 2850453, 2006 U.S. Dist. LEXIS 75873 (N.D. Ohio Sept. 30, 2006), where counsel used a script "to educate [a fact witness] about facts which, whether he ever knew them or not, he did not presently recall, and then put him on the stand to testify ... that he *did* presently recall all of the topics covered in the outline," which the court deemed "tantamount to suborning perjury." *Id.*, 2006 WL 2850453, at *7, 2006 U.S. Dist. LEXIS 75873, at *31.

vi. Leading questions

Next, Mutual complains that Bartlett's counsel repeatedly asked leading questions on direct examination. *See* Fed. R. Evid. 611 ("Leading questions should not be used on the direct examination of a witness except as may be necessary to develop the witness' testimony."). That is true, but the other half of the story is that Bartlett's counsel met with repeated rebukes from this court when they did so, sometimes in response to Mutual's objections (which were mostly sustained) and sometimes *sua sponte* (since Mutual often did not object). Some of those rebukes came in the presence of the jury. It is well established that trial courts have "extensive discretion over the phrasing of questions." *United States v. Hansen*, 434 F.3d 92, 105 (1st Cir. 2006). This court exercised that discretion throughout trial to prevent Bartlett from using leading questions to gain an unfair advantage over Mutual.[44]

If anything, this court may have been too hard on Bartlett's counsel, since some of their leading questions appear, in hindsight, to have been designed to elicit disclosed opinions from Bartlett's experts, while keeping the experts away from related topics that this court had deemed off-limits. In such instances, Mutual still had the opportunity to test the experts' opinions through cross-examination. *See id.* (noting that "thorough cross-examination" may eliminate any prejudice from leading questions).

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[44] "There is, of course, a degree of tolerance for leading questions under certain circumstances." *Hansen*, 434 F.3d at 105. One such circumstance, which arose a few times during this trial, is where an unavailable witness's testimony is presented by deposition, and the leading questions cannot simply be rephrased as they would be during live testimony.

vii. Undisclosed expert opinions

Mutual also argues that Bartlett's counsel repeatedly attempted to elicit undisclosed expert opinions. *See* Fed. R. Civ. P. 26(a)(2)(B)(I) (requiring pre-trial disclosure of "all opinions that the [expert] witness will express"). Again, however, this court went to great lengths to prevent Bartlett's experts from giving such opinions. For example, this court required an advance, written proffer of all opinions that Bartlett's counsel intended to elicit from Dr. Tackett, and went through those opinions one-by-one with the parties to rule out any that had not been properly disclosed before trial (then cautioning Dr. Tackett, before his testimony and outside the presence of the jury, about the opinions deemed off-limits). This court also required Bartlett's counsel to obtain prior approval before eliciting opinions to which they believed Mutual's cross-examination had "opened the door."

Where Bartlett's counsel strayed from the pre-approved opinions, this court did not hesitate to stop them (again, sometimes *sua sponte*) and to strike the testimony or grant other appropriate relief. To the extent that any undisclosed opinions may nonetheless have squeaked past, it happened without objection from Mutual and thus is not a basis for post-trial relief. *See, e.g., Fonten Corp. v. Ocean Spray Cranberries, Inc.*, 469 F.3d 18, 21 (1st Cir. 2006) ("Failure to timely object to an attorney's misconduct will frequently result in the denial of a motion for new trial."). Moreover, Mutual has not shown that any of the key opinions regarding sulindac's risks and benefits were undisclosed, *see* Part III.A.i, *supra*, so it did not suffer any prejudice.

viii. Other attempts to present inadmissible evidence

Mutual also argues that Bartlett's counsel improperly attempted to admit other inadmissible evidence, including testimony that Mutual failed to survey the medical literature for information about sulindac's safety risks, as well as copies of the medical literature and the unpublished Pharmacia report. Again, however, this court rebuffed those attempts, so Mutual suffered no prejudice. Moreover, this court expressly instructed the jury (at Mutual's request) that Mutual's "conduct in seeking ... knowledge" of sulindac's risks was "not relevant to this case." Document no. 378, at 22.

ix. "Missing witness" argument

Next, Mutual argues that Bartlett's counsel violated one of this court's orders by making a "missing witness" argument, i.e., commenting during closing argument on Mutual's failure to call any witnesses. *See Bartlett*, 2010 WL 3156555, at *7 (document no. 278) (stating that parties "may not comment on ... uncalled witnesses unless and until [they] lay[ ] a proper foundation and obtain[ ] this court's permission to do so"). But Bartlett's counsel raised that issue with this court before the closing and obtained permission to make limited comments in that regard. In fact, Mutual conceded that Bartlett's counsel "can comment on the fact that [Mutual] didn't call any witnesses," provided "that's as far as they can go." Document no. 439, at 14.

This court is not persuaded that Bartlett's counsel exceeded the scope of that permission, or otherwise strayed into improper argument. Even if they did, however, this court reminded the jury (*sua sponte*)

immediately after the closing that "while it is accurate to say Mutual did not call witnesses after the plaintiff rested her case, Mutual's counsel did put on a defense in this case, through cross-examination of the plaintiff's witnesses and through its presentation of its own portions of the videotape deposition testimony or read testimony from a transcript that immediately followed the plaintiff's presentation, with respect to witnesses like [Mutual's employee] Dettery." In light of that instruction, Mutual suffered no prejudice.

x. Other improper comments

Finally, Mutual argues that Bartlett's counsel made a number of other improper comments during trial:

- During opening statement, Bartlett's counsel mentioned their own experience in the United States military, which obviously was not relevant. *See* Fed. R. Evid. 401, 402. But this court sustained Mutual's immediate objection to that comment, cutting off Bartlett's counsel before they had finished the point, and instructed Bartlett's counsel, in the presence of the jury, to "talk about the evidence," not to "describe [their] experience, background." Document no. 430, at 89–90. So Mutual suffered no prejudice.

- During opening statement, Bartlett's counsel also noted that Mutual had never apologized to Bartlett. *Id.* at 128. Again, that was not relevant. *See* Fed. R. Evid. 401, 402. But Mutual did not object to that comment, either as it happened or during the sidebar after the opening (when Mutual raised other objections to Bartlett's opening statement). Moreover, this court expressly instructed the jury that Mutual's conduct was "not

at issue" and should not be considered. Document no. 378, at 22. Mutual again suffered no prejudice.

• During both opening and closing, Bartlett's counsel commented that sulindac "stole" Bartlett's freedom, *see* document no. 430, at 89, 91, which Mutual considers an improper reference to its conduct. But, on its face, the comments referred to the drug's effect, not Mutual's conduct. And again, Mutual did not object to the comments. In any event, Mutual suffered no prejudice in light of the instruction just described (regarding Mutual's conduct not being at issue).

• On a number of occasions, Bartlett's counsel referred to the Pharmacia report as the work of Mutual's expert Dr. Stern, who never testified at trial, and as a "draft" of the *Journal of Rheumatology* article. Mutual argues that those comments were unfair and misleading, but this court disagrees. Dr. Stern was, in fact, the report's author and one of Mutual's designated experts. Until the end of trial, when Mutual rested without calling any witnesses, it was unclear whether Mutual would call Dr. Stern. And Dr. Stern acknowledged at his deposition that the published article was based on data from the Pharmacia report, such that he even sought Pharmacia's permission to publish the article.

• During closing argument, Bartlett's counsel incorrectly stated that the FDA "didn't have" the Pharmacia report (whereas the evidence was only that Dr. Stern had not personally provided the report to the FDA). But this court granted Mutual's request for a curative instruction on that point, explaining to the jury that Bartlett's counsel

had mischaracterized the record. In light of that instruction, Mutual suffered no prejudice.

• Bartlett's counsel also argued, during closing argument, that sulindac's warning violated FDA labeling regulations. Again, however, this court granted Mutual's request for a cautionary instruction on that point, telling the jury (consistent with the final jury charge) that "compliance or noncompliance with FDA labeling ... is not necessarily controlling" on the issue of whether sulindac's warning avoided an unreasonable danger, and that "you may give such evidence as much or little weight as you think it deserves." Subject to that instruction (and probably even without it), the argument was permissible. *See* Part III.B.iv, *supra*.

• Bartlett's counsel also stated, during closing argument, that questions by attorneys are not evidence.[45] But that comment tracked this court's jury instructions, *see* document no. 378, at 8–9 ("Questions ... by lawyers are not evidence, unless the witness adopts the facts set forth in the question."), which in turn tracked controlling case law, *see United States v. Cudlitz*, 72 F.3d 992, 1002–03 (1st Cir. 1996) ("questions of counsel are not evidence"). To the extent that it differed at all, this court instructed the jury to "take the law from

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[45] Mutual seems to be concerned primarily with a set of questions about whether Bartlett's experts knew that sulindac was listed as a preferred drug on various drug formularies. But the experts' "no" answers to those questions were not evidence that the formularies actually listed sulindac; they were merely evidence that the experts did not know either way.

the court." Document no. 378, at 9. So, again, Mutual suffered no prejudice.

E. *Cumulative evidence*

The next issue raised by Mutual's Rule 59 motion is whether this court allowed Bartlett to present too much evidence of her severe injuries. Mutual argues, first, that this court should have bifurcated the trial into separate liability and damages phases to prevent such evidence from improperly influencing the liability determination. *See* Fed. R. Civ. P. 42(b) ("For convenience, to avoid prejudice, or to expedite or economize, the court may order a separate trial of one of more separate issues"). This court has already addressed that argument at length in a pre-trial order. *See Bartlett*, 2010 WL 3210724 (document no. 320). As explained there, the party seeking bifurcation bears the burden of proving that it will satisfy the rule's objectives, *see, e.g.*, 8 *Moore's Federal Practice*, § 42.20[8], at 42–55 (3d ed. 2007), and the court has broad discretion in determining whether bifurcation is appropriate, *see, e.g.*, *Lisa v. Fournier Marine Corp.*, 866 F.2d 530, 531 (1st Cir. 1989).

Mutual failed to show that bifurcation was appropriate in this case. Even if the trial had been bifurcated, evidence of SJS/TEN's severity still would have been admissible at the liability phase, to inform the jury's risk/benefit analysis. *See* Fed. R. Evid. 402; *Price*, 142 N.H. at 389, 702 A.2d 330 (jury may consider "the risk of danger posed by [the product's] use"). Moreover, since Mutual put Bartlett to her proof on causation (even though, as already mentioned, that point was essentially undisputed), some evidence of her particular injuries also would have been admissible on that issue, if not also to "paint[ ] the backdrop" of the

case. *Faigin v. Kelly*, 184 F.3d 67, 81 (1st Cir. 1999). As a result, bifurcation likely would have resulted in "duplication of evidence" and would have "force[d] busy doctors from Boston hospitals to make two trips to New Hampshire for this trial," which would have been inefficient. *Bartlett*, 2010 WL 3210724, at *2 (document no. 320); *see also* 8 *Moore's*, *supra*, § 42.20[4][a], at 42–46 (bifurcation is "not the normal course of events, and a single trial will usually be more expedient and efficient").

Short of bifurcation, Mutual argues that "evidence of plaintiff's injuries ... only needed to be presented one time," and that this court erred by allowing "witness after witness to testify, often in graphic detail, about plaintiff's injuries and medical treatment." *See* Fed. R. Evid. 403 (allowing exclusion of relevant evidence "if its probative value is substantially outweighed by the danger of unfair prejudice ... or needless presentation of cumulative evidence"). Each witness, though, had something different to add. Bartlett's ordeal with SJS/TEN caused many different injuries, requiring the involvement of many doctors (with various specialties), and impacting many aspects of her life. No single witness, even Bartlett herself, could have given the jury a full picture of what happened.[46]

It is true that some of the witnesses went into graphic detail about Bartlett's injuries, and that some of the pictures shown to the jury were unpleasant, but that is because Bartlett's injuries were so horrific and, in many respects, far beyond the experience of the

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[46] Indeed, Bartlett spent months of her recovery in a medically induced coma. Mutual contested whether Bartlett could feel pain during that period, which obviously did not help to reduce the amount of pain-related testimony.

average juror. *See* Part III.F, *infra*. There was really no other way for Bartlett to convey to the jury the full extent of her pain and suffering. *See United States v. Morales-Aldahondo*, 524 F.3d 115, 120 (1st Cir. 2008) ("The trial judge's job is to avoid unfair prejudice," not "to scrub the trial clean of all evidence that may have an emotional impact."). This court "balanced the competing concerns of Rule 403 by," for example, reviewing proffered photographs in open court (outside the presence of the jury) and "limiting the number of images presented," as well as by excluding proffered video footage of the type of eye surgery that Bartlett underwent, among other things. *Id.* Mutual has not shown any miscarriage of justice in that regard.

F. *Damages award*

The next issue raised by Mutual's Rule 59 motion is whether the jury awarded Bartlett an excessive amount of compensatory damages. As mentioned earlier, the jury awarded a total of $21.06 million, consisting of $4.56 in special damages that were largely uncontested ($1.25 million for past medical expenses stipulated by the parties, $2.377 million for future medical expenses, and $933,000 for lost wages) plus $16.5 million for pain, suffering, and loss of enjoyment of life. Mutual argues that the amount, and particularly the pain and suffering component, was so high as to be "undoubtedly punitive" and "based purely on the jury's passion and prejudice." This court disagrees. While substantial, the award was within the acceptable range, in light of the horrific injuries that Bartlett suffered. Given this court's instruction on the issue in the final jury charge, there is no reason

to think that the pain and suffering award was punitive.[47]

"District courts may grant a motion for new trial" based on the amount of damages "only if the award exceeds any rational appraisal or estimate of the damages that could be based on the evidence before the jury and is grossly excessive, inordinate, shocking to the conscience of the court, or so high that it would be a denial of justice to permit it to stand." *Franceschi v. Hosp. Gen. San Carlos, Inc.*, 420 F.3d 1, 5 (1st Cir. 2005); *see also Bielunas v. F/V Misty Dawn, Inc.*, 621 F.3d 72, 80 (1st Cir. 2010) ("only rarely and in extraordinary circumstances will [courts] veto the jury's decision"). That is a "weighty burden" for Mutual to meet. *Bielunas*, 621 F.3d at 80. This court cannot "jettison a damage award simply because" it is "generous in comparison to other (hand-picked) cases," or in comparison to what the court might have awarded. *Id.* at 80–82.

No one who witnessed the trial in this case could deny the horror of Bartlett's injuries. To name just some of them: Bartlett suffered burns and lost skin over nearly two-thirds of her body; she was in a medically induced coma for months; she lost her sight (despite 12 eye surgeries, to date, attempting to save it, and likely many more to come); she lost the ability to have sexual intercourse due to vaginal injuries; she

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[47] This court instructed the jury (at Mutual's request) that it was "not permitted to award punitive damages or any other money damages for the purpose of punishing Mutual or making an example of it for the public good or for the purpose of preventing Mutual and others from similar conduct." Document no. 378, at 27; *see also Gentles*, 619 F.3d at 82 ("juries are presumed to follow [the court's] instructions").

lost the ability to eat normally due to esophageal stricture (requiring multiple surgeries to stretch the esophagus so that she can eat safely at all); she lost the ability to engage in aerobic activities (in which she had previously been an avid participant) due to lung injuries; she suffered scarring to her face, back, anus, and vagina; and she suffers from post-traumatic stress disorder. Children, she said, are scared of her appearance. And at 50 years old, she is expected to live with her injuries for more than 30 years.

"There is," of course, "no mathematical formula for determining the monetary equivalent of non-economic injuries." *Bielunas*, 621 F.3d at 80. Nor is there any "one 'correct' sum, but, rather, a range of acceptable awards." *Blinzler v. Marriott Int'l, Inc.*, 81 F.3d 1148, 1161–62 (1st Cir. 1996). In many cases, "the spread between the high and low ends of the range will be great. The choice within the range" is "largely within the jury's ken." *Id.* at 1162. That is indeed the case here. The jury's choice to award $16.5 million for Bartlett's pain and suffering—less than four times her special damages—was a rational response to the evidence. While Mutual has cited cases where juries awarded much less for similar injuries, Bartlett has cited cases where juries awarded much more. Her award fell within the "wide universe of acceptable awards," *id.*, and was neither shocking to the conscience nor unjust to Mutual.[48]

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[48] Our court of appeals ruled in *Whitfield v. Melendez-Rivera*, 431 F.3d 1 (1st Cir. 2005), that $3 million was the most a plaintiff could recover for pain and suffering after being shot in the leg and thereafter dealing with a "weak knee" and "limited range of motion" (albeit not enough to prevent him from "pass[ing] the Navy's physical readiness test"). *Id.* at 16–17. Having witnessed Bartlett's testimony firsthand and considered the other evidence

G. *Cumulative error*

The final issue raised by Mutual's Rule 59 motion is cumulative error. Mutual argues that the combined effect of the errors discussed above warrants a new trial, even if none of the errors individually would. As already discussed, however, many of the errors that Mutual cites were not errors at all. *See, e.g., Williams v. Drake*, 146 F.3d 44, 49 (1st Cir. 1998) ("cumulative-error analysis is inappropriate when a party complains of the cumulative effect of non-errors"). Moreover, to the extent that errors occurred, they did not cause any significant prejudice. Mutual has not "come close to [showing] the critical mass [of errors] necessary to cast a shadow upon the integrity of the verdict." *United States v. Sepulveda*, 15 F.3d 1161, 1196 (1st Cir. 1993).

IV. *Conclusion*

For the reasons set forth above, Mutual's motion for judgment as a matter of law[49] and its motion for a new trial[50] are both DENIED.

SO ORDERED.

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presented at trial, this court has no doubt that her pain and suffering surpasses that endured by the *Whitfield* plaintiff by many orders of magnitude.

[49] Document no. 395.

[50] Document no. 394.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett, et al.

v. Civil No. 08-cv-358-JL

Mutual Pharmaceutical Co., Inc., et al.

JUDGMENT

In accordance with the following, judgment is hereby entered:

1. Orders by United States District Judge Joseph N. Laplante dated October 21, 2008, February 25, 2010, May 18, 2010, July 12, 2010 (and orders on reconsideration dated July 30, 2010 and August 12, 2010), August 11, 2010, August 12, 2010, and September 14, 2010; and,

2. The Jury Verdict returned on September 8, 2010, wherein the jury found in favor of the plaintiff, Karen L. Bartlett, as against the defendant, Mutual Pharmaceutical Company, Inc., in the amount of Twenty-One Million Sixty Thousand Dollars ($21,060,000), consisting of One Million Two Hundred Fifty Thousand Dollars ($1,250,000) in past medical expenses, Two Million Three Hundred Seventy-Seven Thousand Dollars ($2,377,000) in future medical expenses, Nine Hundred Thirty-Three Thousand Dollars ($933,000) in lost wages, and Sixteen Million Five Hundred Thousand Dollars ($16,500,000) in pain, suffering, and loss of enjoyment of life, plus (1) pre-

judgment interest pursuant to N.H. Rev. Stat. §§ 336:1, 524:1-a, 542:1-b computed as directed in Linteau v. Gauthier, 142 N.H. 460 (1997) and Nault v. N & L Development Company, 146 N.H. 35 (2001); and (2) post-judgment interest thereon pursuant to 28 U.S.C. § 1961.

By the Court,

/s/ Daniel J. Lynch

Daniel J. Lynch
Chief Deputy Clerk

September 20, 2010

cc: Keith Jensen, Esq.
Eric Roberson, Esq.
Christine Craig, Esq.
Bryan Ballew, Esq.
Patrick J. O'Neal, Esq.
Timothy Beaupre, Esq.
Stephen Judge, Esq.
Joseph Thomas, Esq.
Paul J. Cosgrove, Esq.
Pierre Chabot, Esq.
Jeffrey Geoppinger, Esq.
Linda Maichl, Esq.

Approved As to Form:

_____
Joseph N. Laplante
United States District Judge

United States District Court, D. New Hampshire.

KAREN L. BARTLETT,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.

Civil No. 08-cv-358-JL.

July 12, 2010

OPINION & ORDER

JOSEPH N. LAPLANTE, District Judge.

The question in this case is whether a manufacturer may be held liable for injuries caused by a prescription drug. Plaintiff Karen Bartlett, who took the generic drug Sulindac and suffered severe side effects, brought suit against the drug's manufacturer, Mutual Pharmaceutical Company, asserting state-law claims of strict products liability, negligence, and fraud. She alleges, in particular, that Sulindac is an unreasonably dangerous product and that Mutual should have strengthened the drug's safety warning in light of information reported in the medical literature. This court has jurisdiction under 28 U.S.C. § 1332(a)(1) (diversity), because Bartlett is a New Hampshire citizen and Mutual is located in Pennsylvania. Earlier in the case, this court denied Mutual's motion for judgment on the pleadings, *see* Fed. R. Civ. P. 12(c),

rejecting the argument that Bartlett's claims were pre-empted by federal law. *See Bartlett v. Mut. Pharm. Co.*, 659 F. Supp. 2d 279 (D.N.H. 2009).

Both parties have now moved for summary judgment. *See* Fed. R. Civ. P. 56. After hearing oral argument, this court grants each motion in part. To the extent that Bartlett's claims are based on Mutual's alleged failure to warn of safety risks, Mutual is entitled to summary judgment because Bartlett cannot prove that conduct caused her injuries. Her doctor, who is the person Mutual had a duty to warn, prescribed Sulindac without reading or relying upon its warning label. Thus, no matter what the label said, it would not have affected the doctor's decision to prescribe the drug or otherwise prevented Bartlett's injuries. But to the extent that her claims are based not on the alleged failure to warn, but on the theory that Sulindac is an unreasonably dangerous product, they present a genuine dispute of material fact that must be resolved at trial. Finally, Bartlett is entitled to summary judgment on some of Mutual's affirmative defenses.

I. *Applicable legal standard*

Summary judgment is appropriate where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). An issue is "genuine" if it could reasonably be resolved in either party's favor at trial, and "material" if it could sway the outcome under applicable law. *Mulvihill v. Top–Flite Golf Co.*, 335 F.3d 15, 19 (1st Cir. 2003). In making this determination, the "court must scrutinize the record in

the light most flattering to the party opposing the motion, indulging all reasonable inferences in that party's favor." *Id.* On cross-motions for summary judgment, this standard is applied to each party's motion separately. *See, e.g., Am. Home Assurance Co. v. AGM Marine Contractors, Inc.*, 467 F.3d 810, 812 (1st Cir. 2006).

II. *Background*[1]

In December 2004, Bartlett sought medical treatment for pain in her right shoulder. Her doctor, Tahsin Ergin, prescribed a non-steroidal anti-inflammatory drug ("NSAID") called Clinoril. Bartlett took the prescription to a pharmacy in Plaistow, New Hampshire, which filled it with Sulindac, a generic version of the drug, manufactured by Mutual. Within weeks, she went to a local emergency room complaining of skin blisters, a fever, eye irritation, and other symptoms. She was soon diagnosed with Stevens–Johnson syndrome ("SJS") progressing to toxic epidermal necrolysis ("TEN"), a serious and potentially fatal condition characterized by necrosis of the skin and mucous membranes. *See Dorland's Illustrated Medical Dictionary* 1872 (31st ed. 2007). She spent about three months in the hospital recovering, two of them in a medically induced coma, and emerged with permanent injuries, including blindness.

More than a year before these events, an international medical journal published a study of the

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[1] This summary is based on undisputed facts in the record. To the extent that the summary judgment motions implicate disputed facts, this court will discuss them in the appropriate part of the analysis, drawing the required inferences in favor of the non-moving party.

link between NSAIDs and SJS/TEN. The study revealed that, from 1980 to 1997, Sulindac had 89 reported cases of SJS/TEN in the Food and Drug Administration's ("FDA") adverse event reporting system, more than any other NSAID on the market and all but four drugs of any kind. *See* Maja Mockenhaupt et al., *The Risk of SJS and TEN Associated with NSAIDs: A Multinational Perspective,* 30 Journal of Rheumatology 2234–2240 (Oct. 2003). Mutual was not aware of that study, however, because it had not been monitoring the medical literature for information about Sulindac's safety risks. Mutual believed that the manufacturer of Clinoril, the brand-name version of the drug, was responsible for such monitoring.

At the time of Bartlett's prescription, Mutual's generic version of Sulindac had the same FDA-approved package insert, or warning label, as Clinoril. The label expressly listed SJS/TEN as potential adverse reactions in its "Adverse Reactions" section. In its "Warnings" section, however, the label did not mention SJS/TEN by name. Rather, it stated as follows:

Hypersensitivity

Rarely, fever and other evidence of hypersensitivity (see ADVERSE REACTIONS) including abnormalities in one or more liver function tests and severe skin reactions have occurred during therapy with sulindac. Fatalities have occurred in these patients. Hepatitis, jaundice, or both, with or without fever, may occur within the first one to three months of therapy. Determination of liver function should be considered whenever a patient on therapy with sulindac develops unexplained fever, rash or other dermatologic reactions

or constitutional symptoms. If unexplained fever or other evidence of hypersensitivity occurs, therapy with sulindac should be discontinued.[2]

Dr. Ergin admitted at his deposition that he never reviewed Mutual's Sulindac label before treating Bartlett and that "nothing about it influenced [his] prescribing of the drug" or what he told Bartlett about it. When asked if he reviewed the identical Clinoril label before treating Bartlett, Dr. Ergin responded "not in detail, no." He then admitted that he never read the part of the Clinoril label that listed SJS/TEN as potential adverse reactions, nor the part that warned of "hypersensitivity" and "severe skin reactions" that have caused fatalities.

Even without reading the warning label, Dr. Ergin knew from his medical background that Sulindac and other NSAIDs carried some risk of causing SJS/TEN. But it was not his usual practice to discuss that risk with patients, and he did not do so with Bartlett. If, however, there had been "strong warnings in place" about "what may well be [a] higher risk of severe reactions like SJS and TEN with Sulindac," Dr. Ergin claims that he likely would have prescribed a different drug for Bartlett that carried less risk of SJS/TEN. He admitted, however, that he still prescribes Sulindac on rare occasions, even after learning of Bartlett's ordeal.

Bartlett brought this suit against Mutual in New Hampshire superior court in January 2008, asserting state-law claims of strict products liability based on failure to warn of safety risks (Count 1), strict products

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[2] As discussed in Part III, *infra*, the parties disagree over whether this paragraph, together with the cross-referenced list of adverse reactions, amounted to an adequate warning of SJS/TEN.

liability based on defective design (Count 2), fraud (Count 3), and negligence based on both failure to warn and defective design (Count 6).[3] She alleges, in particular, that Sulindac's safety risks outweigh its medical benefits, making it an unreasonably dangerous product. She also alleges that Mutual should have strengthened Sulindac's safety warning in light of the study mentioned above and other reports in the medical literature about the connection between Sulindac and SJS/TEN.

After removing the case to this court, Mutual moved for judgment on the pleadings, arguing that all of Bartlett's claims were pre-empted by the Hatch–Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations issued thereunder. Specifically, Mutual argued that federal law prohibits a manufacturer from unilaterally strengthening the safety warning for a generic drug approved by the FDA, because the warning must remain identical to that of the brand-name drug. This court denied the motion, concluding that federal law allows such changes and thus does not pre-empt Bartlett's claims. *See Bartlett*, 659 F. Supp. 2d at 279; *accord Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), *petition for cert. filed*, 78 U.S.L.W. 3522 (U.S. Feb. 19, 2010) (No. 09–993).

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[3] Bartlett also asserted a gross negligence claim (Count 7). But "New Hampshire law does not distinguish causes of action based on ordinary and gross negligence," *Barnes v. N.H. Karting Ass'n*, 128 N.H. 102, 108, 509 A.2d 151 (1986), so this court will not separately discuss the gross negligence claim. Bartlett voluntarily dismissed her other claims, for breach of warranty (Counts 4 and 5).

As the case proceeded, the parties engaged in a series of discovery disputes. *See, e.g., Bartlett v. Mut. Pharm. Co.*, 2009 DNH 166 (imposing sanctions against Mutual for the late production of certain FDA filings). With discovery now complete and trial scheduled for August 2010, Mutual has moved for summary judgment on all claims. *See* Fed. R. Civ. P. 56(b). Bartlett, in turn, has moved for partial summary judgment on various issues, some of which overlap with those raised by Mutual. *See* Fed. R. Civ. P. 56(a). This court will address each issue in turn, beginning with the key issues on which both parties seek summary judgment (i.e., the adequacy of Sulindac's safety warning and whether its alleged inadequacy caused Bartlett's injuries) and then turning to the other issues that they have raised separately.

III. ***Adequacy of the safety warning***

The first issue, on which both parties seek summary judgment, is whether Mutual's Sulindac label adequately warned doctors of the risk of SJS/TEN. Bartlett has the burden of proving its inadequacy as an essential element of her claims for strict liability (Count 1) and negligence (Count 6) based on failure to warn. *See, e.g., Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652 (1st Cir. 1981) (applying New Hampshire law); *see also Nelson v. Dalkon Shield Claimants Trust*, No. 84–276–SD, 1994 WL 255392 (D.N.H. June 8, 1994). "An adequate warning is one reasonable under the circumstances" to notify the doctor of the drug's safety risks. *Brochu*, 642 F.2d at 657. The adequacy of a given warning must be judged in the light of the facts known at the time, without the benefit of hindsight. *Id.* "A warning may be

inadequate in factual content, in expression of the facts, or in the method by which it is conveyed." *Id.*

Bartlett argues that the Sulindac label was inadequate as a matter of law because it failed to mention SJS/TEN in its "Warnings" section, failed to list the severe complications that SJS/TEN can cause (e.g., blindness, coma), and failed to identify the steps that should be taken if they occur, as required by FDA regulations. *See* 21 C.F.R. § 201.57(e) (2004).[4] Mutual, in contrast, argues that the label was adequate as a matter of law because it expressly listed SJS/TEN in its "Adverse Reactions" section and then cross-referenced them in its "Warnings" section, where it discussed the risk of "hypersensitivity" and "severe skin reactions" that have caused fatalities, as well as the steps that should be taken if "evidence of hypersensitivity occurs." Both parties have proffered expert testimony in support of their respective positions.

While neither party is entitled to summary judgment on this genuinely disputed issue, Mutual is much closer to meeting the summary judgment standard than Bartlett. In *Guevara v. Dorsey Labs.*, 845 F.2d 364 (1st Cir. 1988), the court of appeals reversed a jury's finding that a drug label was inadequate where the label warned of "hypersensitivity" but "did not specifically warn of the

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[4] Mutual argues that this FDA regulation applies only to manufacturers of brand-name drugs, not generic versions. But this court already rejected that argument in its earlier preemption ruling. *See Bartlett*, 659 F. Supp. 2d at 289 n. 13, 298 n. 25. In any event, the regulation is not dispositive of the label's adequacy. *See* Part VIII, *infra* (explaining that violation of FDA safety regulations is evidence of negligence, but not negligence *per se*).

kind of [skin] reaction" the plaintiff suffered, which caused blisters and scarring. *Id.* at 366. The court reasoned that "the warning, read as a whole, clearly tells doctors" of the risk of such a reaction because, according to the plaintiff's own expert, "a doctor warned about hypersensitivity should know that it could be manifested as a skin rash." *Id.* at 366–68. The court therefore ruled as a matter of law that a more "detailed admonition" was not required. *Id.* at 366.

Of course, SJS/TEN is far more serious than a skin rash. It has an estimated mortality rate of 30 to 60 percent and, for those who survive, can cause a range of severe and lifelong health problems, as it has for Bartlett. Nevertheless, some courts have applied reasoning similar to *Guevara's* in SJS/TEN cases, deeming a drug's safety warning, phrased similarly to the one in this case, adequate as a matter of law. *See Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 573 (D. Md. 2006) ("One might prefer to have SJS/TEN listed in the Warnings section, but the present structure cannot be said to be unreasonable merely because it requires the reader to make a cross-reference."); *see also Hall v. Merck, Sharp & Dohme*, 774 F. Supp. 604, 606–08 (D. Kan. 1991); *Williams v. Ciba–Geigy Corp.*, 686 F. Supp. 573, 578–80 (W.D. La. 1988); *Serna v. Roche Labs.*, 101 N.M. 522, 684 P.2d 1187, 1188–1190 (N.M. Ct. App. 1984).

This court is not persuaded, however, that summary judgment is appropriate on the current record. Even assuming *arguendo* that a reasonable doctor would have understood Sulindac's warning of "hypersensitivity" and "severe skin reactions" as a cross-reference to SJS/TEN, the question remains

whether the warning should have been clearer, more prominent, and more detailed. Given the severity of SJS/TEN and the study indicating that Sulindac had more reported cases than any other NSAID and all but four other drugs, that question cannot be taken away from the jury. *See Brochu*, 642 F.2d at at 658–59 (affirming jury's finding that drug label was inadequate where it did not refer to key study indicating higher risk of a severe reaction); *see also Marchant v. Dayton Tire & Rubber Co.*, 836 F.2d 695, 701 (1st Cir. 1988) ("questions regarding the adequacy of warnings are almost always an issue to be resolved by a jury") (quotation omitted). Accordingly, this court denies the parties' cross-motions for summary judgment on this issue.

IV. *Causation*

The second issue on which both parties seek summary judgment is whether Mutual's alleged failure to issue a stronger warning caused Bartlett's injuries. Bartlett has the burden of proving causation as an essential element of her claims for strict liability (Count 1) and negligence (Count 6) based on failure to warn. *See, e.g., LeFavor v. Ford*, 135 N.H. 311, 313, 604 A.2d 570 (1992); *Brochu*, 642 F.2d at 659; *Nelson*, 1994 WL 255392, at *8. Causation has two components under New Hampshire law: cause-in-fact and legal cause. *Carignan v. N.H. Int'l Speedway, Inc.*, 151 N.H. 409, 414, 858 A.2d 536 (2004). "Cause-in-fact requires the plaintiff to show that the injury would not have occurred but for the negligent conduct." *Id.* Legal cause, in turn, "requires the plaintiff to establish that the negligent conduct was a substantial factor in bringing about the harm." *Id.* In this context, that means Bartlett "must prove that had the learned

intermediary [i.e., her doctor[5]] been warned adequately, the drug would not have been used, or would have been used differently." 5 Louis R. Frumer & Melvin I. Friedman, *Products Liability* § 50.05[4], at 50–84 (2010).

In moving for summary judgment on this issue, Bartlett argues that the deposition testimony of her treating physician, Dr. Ergin, proves that he would have prescribed a different drug with a lower risk of SJS/TEN if he had been given a stronger warning by Mutual of "what may well be [a] higher risk of severe reactions like SJS and TEN with Sulindac." Even if true, however, that addresses only the last link in the causal chain. The logically prior question, which Mutual raises in its own summary judgment motion, is whether a stronger warning by Mutual would have reached Dr. Ergin's attention in the first place, enabling it to affect his decision in that manner. As explained below, Bartlett has presented no evidence to establish that link in the causal chain. Indeed, the evidence in the record is to the contrary. Mutual is therefore entitled to summary judgment on this issue.

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[5] It is well established that a manufacturer's duty to warn of a drug's safety risks "requires that the physician, not the patient, be warned." *Brochu*, 642 F.2d at 661. This is sometimes called the "learned intermediary" rule, because its underlying rationale "is that the prescribing physician, as the 'learned intermediary' standing between the manufacturer and the consumer/patient, is generally in the best position to evaluate the [drug's] potential risks and benefits ... and to advise the patient accordingly." *Nelson*, 1994 WL 255392, at *4 (quoting *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992)).

A. *Bartlett's doctor never reviewed the warning label*

At his deposition, Dr. Ergin made clear that he never reviewed Mutual's Sulindac label before treating Bartlett and that nothing about it influenced his decision to prescribe the drug or what he told her about it. Instead, he relied on his background knowledge of the drug's safety risks, including his knowledge that it could cause SJS/TEN. Thus, even assuming *arguendo* that Mutual had a duty to strengthen the SJS/TEN warning on its Sulindac label, that stronger warning would not have affected Dr. Ergin's decision or prevented Bartlett's injuries. *See, e.g., Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (affirming summary judgment based on lack of causation where plaintiff's "doctor testified that he did not read the warning label"); *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (same); 5 Frumer & Friedman, *supra*, § 50.05[4], at 50–88 (noting that "most courts will find an absence of causation as a matter of law" where "the physician testifies that he or she never read the warnings given").

Bartlett argues that the jury could nevertheless find causation based on Dr. Ergin's review of the identical label for the brand-name drug, Clinoril. But Dr. Ergin testified at his deposition that he never reviewed the Clinoril label either ("no, not in detail" was his precise response). Even if one infers from that response that Dr. Ergin may have given the label a cursory review, he proceeded to acknowledge that he never read the part of the label that listed SJS/TEN as potential adverse reactions (in the "Adverse Reactions" section), nor the part that warned of "hypersensitivity" and "severe skin reactions" that have caused fatalities

(in the "Warnings" section). Thus, even if those warnings had been stronger, as Bartlett alleges they should have been, they would not have reached Dr. Ergin's attention or prevented Bartlett's injuries.

Moreover, Bartlett has presented no evidence that if Mutual had strengthened its Sulindac label, the FDA would have required corresponding changes to the Clinoril label.[6] So far as the record indicates, that sequence of events (i.e., unilateral changes to a generic drug label, followed by FDA-mandated changes to the brand-name drug label) would have been highly unusual, if not unprecedented. Indeed, Bartlett herself points to this lack of precedent in arguing that it would be speculative for Mutual's experts to opine that the FDA would *not* have taken such action.[7] But she, too, has offered nothing but speculation. Since it is a

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[6] Even now, more than five years after Bartlett's prescription, the FDA has not mandated the sort of label changes that Dr. Ergin said would have influenced his prescription decision. In response to a citizen's petition filed by a group of doctors in 2005, the FDA required that all NSAID labels (including Sulindac's) use the following language in their "Warnings" section:

NSAIDs, including [sulindac], can cause serious skin adverse events such as exfoliative dermatitis, Stevens–Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Nothing in that warning suggests "what well may be [a] higher risk of severe reactions like SJS and TEN with Sulindac" (to use Dr. Ergin's phrase). If anything it implies that all NSAIDs have a similar risk of SJS/TEN. Thus, even if the label change is admissible (which the parties dispute, *see* Fed. R. Evid. 407), it hurts rather than helps Bartlett on the issue of causation.

[7] Document no. 151 at 6.

plaintiff's burden to prove causation, that evidentiary gap is fatal to any causation theory based on the Clinoril label. *See Lockridge v. Univ. of Me. Sys.*, 597 F.3d 464, 471 n. 6 (1st Cir. 2010) ("unsupported speculation ... is insufficient to forestall summary judgment").

Bartlett attempts to fill the evidentiary gap by pointing to Mutual's legal position, which is that FDA regulations require a generic drug's label to remain the same as that of the brand-name drug. She seems to be arguing that Mutual is therefore estopped from contesting whether changes to the Sulindac label would have resulted in corresponding changes to the Clinoril label. But Mutual's position is that FDA regulations prohibit unilateral changes to generic drug labels, not that they require the brand-name drug label to copy such changes. In any event, Bartlett argued against Mutual's position in her objection to the earlier motion for judgment on the pleadings, and this court agreed with her. *See Bartlett*, 659 F. Supp. 2d at 304 (ruling that federal regulations "did not in fact require the generic drug's labeling to remain the same as [brand-name] drug's post-approval"). She cannot use her opponent's unsuccessful legal theory as a substitute for evidence of causation.

Bartlett also argues that she is not required to present evidence of causation because there is "a rebuttable presumption in favor of the plaintiff that a physician would have heeded an adequate warning" if the drug's manufacturer had given one. *Garside*, 976 F.2d at 80 (citing Restatement (Second) Torts, § 402A, comment j). Whether that so-called "heeding presumption" applies under New Hampshire law is questionable. *See Wilson v. Bradlees of New Eng., Inc.*,

250 F.3d 10, 16 (1st Cir. 2001) (declining to apply heeding presumption because the New Hampshire Supreme Court had not yet done so). But even assuming *arguendo* that it applies, the presumption has been rebutted by Dr. Ergin's deposition testimony, which makes clear that he did not review Mutual's Sulindac warning label before prescribing the drug to Bartlett and thus would not have heeded any changes that Mutual made to it.[8]

Finally, Bartlett argues that summary judgment is inappropriate because the jury could reject Dr. Ergin's testimony on credibility grounds. But that is always true of any witness's sworn statements submitted in support of summary judgment. A party's "bare assertion that the opposing party's uncontroverted evidence might be disbelieved is insufficient to resist judgment as a matter of law on an issue as to which the party resisting judgment bears the burden of proof." *Favorito v. Pannell*, 27 F.3d 716, 721 (1st Cir. 1994); *see also Levesque v. Doocy*, 560 F.3d 82, 87 (1st Cir. 2009) ("[A] mere challenge to the credibility of a movant's witness without any supporting evidence does not raise a trialworthy issue of fact.").

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[8] Nor is Bartlett saved by the principle "that a physician's carelessness ... should not relieve a drug manufacturer of liability if the manufacturer's failure to warn adequately may have contributed to that carelessness." *Brochu*, 642 F.2d at 660 (quoting *McCue v. Norwich Pharmacal Co.*, 453 F.2d 1033, 1035 (1st Cir. 1972)). Nothing in the record suggests that Mutual's alleged failure to warn of SJS/TEN contributed to Dr. Ergin's decision not to read Sulindac's warning label or, for that matter, that he was careless in not doing so. As discussed above, Dr. Ergin already knew from his medical background that Sulindac could cause SJS/TEN.

Bartlett points to "a line of cases holding that a physician's statement about what s/he would have done in the face of an adequate warning raises a credibility issue which must be decided by a jury," because that sort of "hindsight opinion is not conclusive." *Garside*, 976 F.2d at 83 n. 9 (quoting *Doe v. Miles Lab., Inc.*, 927 F.2d 187, 195 n. 32 (4th Cir. 1991)). But Bartlett is the one who moved for summary judgment based on Dr. Ergin's opinion testimony about what he hypothetically would have done in response to a stronger warning. (She apparently sees credibility as no barrier to summary judgment in her *favor* on this issue.) Mutual, in contrast, moved for summary judgment based on Dr. Ergin's factual testimony about what he actually did before prescribing the drug. Such testimony *is* conclusive where, as here, it is not controverted by other evidence.

B. *Non-label theories*

At oral argument, this court also explored whether a stronger warning by Mutual could have reached Dr. Ergin's attention through some other means (apart from the label). Although Bartlett had not asserted any "non-label" theories of causation in her summary judgment objection, she seized the opportunity to do so when the court raised the theories at oral argument, arguing that she or Dr. Ergin would have seen the warning if Mutual had created a medication guide for Sulindac users, sent a "Dear Doctor" letter directly to healthcare providers, filed a citizen's petition with the FDA, or launched an educational campaign. Ordinarily, this court will not consider theories raised for the first time at oral argument, out of fairness to the adverse party. *See, e.g., Johnson v. Gen. Dynamics*

Info. Tech., Inc., 675 F. Supp. 2d 236, 241 n. 3 (D.N.H. 2009); *Doe v. Friendfinder Network, Inc.*, 540 F. Supp. 2d 288, 304 n. 19 (D.N.H. 2008).[9]

Even if considered on the merits, however, Bartlett's "non-label" theories would not prevent summary judgment on the issue of causation:

- Starting with the patient medication guide, it is well established that a manufacturer's duty to warn of a drug's safety risks "requires that the physician, not the patient, be warned." *Brochu*, 642 F.2d at 661; *see also Nelson*, 1994 WL 255392, at *4. Since Mutual had no duty to warn Bartlett directly, its failure to issue such a warning (in the form of a medication guide or otherwise) cannot serve as the basis for a finding of causation.

- Turning to the "Dear Doctor" letter, Bartlett admitted at oral argument that there is no evidence about whether Dr. Ergin has a practice of reading such letters. Moreover, there is little, if any, evidence about the process for distributing such letters. *See, e.g., Demahy*, 593 F.3d at 444–45 & n. 108 (suggesting that "generic manufacturers cannot send 'Dear Doctor' letters without prior FDA approval"). With the record in this undeveloped state, any causation theory based on a "Dear Doctor" letter is purely speculative.

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[9] Even after oral argument, both parties continued to present new theories on various summary judgment issues, inserting them (somewhat incongruously) into their briefs on the pending motions in limine. Bartlett, for example, argued that a stronger warning could have reached Dr. Ergin's attention through an FDA press release or health advisory. Since those arguments are untimely and improperly raised, this court will not consider them.

- Bartlett also suggested at oral argument that Mutual should have filed a citizen's petition with the FDA requesting changes to the Sulindac and Clinoril labels, such as a "black box" warning of SJS/TEN. As she acknowledged, however, that theory puts her back in the same predicament discussed above, because Dr. Ergin never would have seen those label changes (even assuming *arguendo* that the FDA would have approved them).

- Finally, Bartlett suggested that Mutual should have launched an educational campaign to promote early monitoring of Sulindac's side effects. She emphasized at oral argument that the manufacturer of Bextra, another NSAID linked to SJS/TEN, advocated such a campaign to Canadian regulators. For purposes of causation, however, the key question is not whether Mutual should have advocated such a campaign, but what would have happened if it did. Because there is no evidence on that point, it is pure speculation to say that such a campaign would have prevented Bartlett's injuries.

All of these "non-label" theories, moreover, rest upon a dubious proposition: that even if Mutual had strengthened the SJS/TEN warning on its Sulindac label (i.e., disclosing prominently in the "Warnings" section that Sulindac had more reported cases of SJS/TEN than any other NSAID and all but four other drugs, and listing all the potential complications of SJS/TEN), that still would have been a legally inadequate warning unless Mutual took additional steps beyond the label to disseminate such information. Bartlett has not identified any authority or evidence for that proposition. Indeed, as already

discussed, it is debatable whether Mutual even had a duty to include such detailed information in the label itself. *See* Part III, *supra*.

In sum, Bartlett has not met her burden of coming forward with "specific facts, in suitable evidentiary form, to establish the presence of a trialworthy issue" as to whether Mutual's alleged failure to warn caused her injuries. *Clifford v. Barnhart*, 449 F.3d 276, 280 (1st Cir. 2006); *see also* Fed. R. Civ. P. 56(e)(2). Her causation theories "rest[ ] merely upon conclusory allegations, improbable inferences, and unsupported speculation." *Meuser v. Fed. Express Corp.*, 564 F.3d 507, 515 (1st Cir. 2009). Mutual is accordingly entitled to summary judgment on Bartlett's claims of strict products liability (Count 1) and negligence (Count 6) based on failure to warn.

C. *Defective design claims*

After oral argument, this court ordered supplemental briefing to help determine whether this causation problem is fatal to Bartlett's other claims of strict products liability (Count 2) and negligence (Count 6) based on defective design. Mutual argues those claims, too, are really failure-to-warn claims because the only "defect" that Bartlett alleges is an inadequate safety warning. But that is not accurate. Bartlett also alleges that Sulindac is defective because its safety risks outweigh its medical benefits, making it an unreasonably dangerous product.[10] As the New Hampshire Supreme Court has explained:

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[10] Bartlett further alleges that Mutual should have removed Sulindac from the market in light of its unreasonable dangerousness. This court need not consider that issue here, though, because both parties agree that defective design claims do not require such a finding.

> A design defect exists when the product is manufactured in conformity with the intended design but the design itself poses unreasonable dangers to consumers. A strict liability action based upon a theory of defective design may be joined with an action grounded in negligence. To maintain a products liability claim based on defective design, a plaintiff must prove: (1) that the design of the product created a defective condition unreasonably dangerous to the user; (2) that the condition existed when the product was sold ...; (3) that the use of the product was reasonably foreseeable by the manufacturer; and (4) that the condition caused injury to the user or the user's property.

Trull v. Volkswagen of Am., Inc., 145 N.H. 259, 264, 761 A.2d 477 (2000) (citations omitted). Such a claim is independent of any inadequacy in the product's safety warning and can be brought as an alternative ground for recovery under New Hampshire law. *See Brochu*, 642 F.2d at 657 (explaining that it is "neither illogical nor inconsistent" to bring both claims in a case involving prescription drugs).

This is not to say, however, that Mutual cannot use Sulindac's safety warning as part of its defense against Bartlett's defective design claims. The New Hampshire Supreme Court has said that "[s]ome products are so important that a manufacturer may avoid liability [for defective design] as a matter of law if he has given proper warnings." *Thibault v. Sears, Roebuck & Co.*, 118 N.H. 802, 808, 395 A.2d 843 (1978) (citing two cases that involved prescription drugs).

This principle is explained more fully in the *Restatement (Second) of Torts:*

> **Unavoidably unsafe products.** There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability

> for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A, cmt. k (1965); *see also Bellotte v. Zayre Corp.*, 116 N.H. 52, 55, 352 A.2d 723 (1976) (citing cmt. k); *Brochu*, 642 F.2d at 656 (same).

Because this comment "is traditionally viewed as an exception and a defense to strict liability, courts generally place the initial burden of proving the various ... factors on the defendant," meaning that "plaintiff's burden of proof on his or her prima facie case remains the same as in any products liability case." 1 Frumer & Friedman, *supra*, § 8.07[5], at 8–296; *see also, e.g., Castrignano v. E.R. Squibb & Sons, Inc.*, 900 F.2d 455, 457 (1st Cir. 1990) (applying Rhode Island law). This court predicts that the New Hampshire Supreme Court would follow that majority approach, particularly since it has referred to the exception as a way "that a manufacturer may avoid liability," *Thibault*, 118 N.H. at 808, 395 A.2d 843, and has said that "proof of an alternative design" (i.e., avoidability) is not an essential element that must be proved by the plaintiff in a defective design case. *Vautour v. Body Masters Sports Indus., Inc.*, 147 N.H. 150, 156, 784 A.2d 1178 (2001).

Applying these principles to the current record, this court concludes that Bartlett has presented enough evidence (primarily in the form of expert testimony) to create a trialworthy issue as to whether Sulindac is unreasonably dangerous and whether that defective condition caused her injuries. Assuming *arguendo* that

the jury finds for her on those points, Mutual might nonetheless be able to avoid liability for defective design if it can prove, as an affirmative defense, that Sulindac is unavoidably unsafe and had an adequate safety warning. As explained above, however, the adequacy of Sulindac's safety warning is a matter of genuine dispute on this record. *See* Part III, *supra*. Because "a product without a proper warning, even if otherwise unavoidably unsafe, does not qualify for the strict liability exemption," 1 Frumer & Friedman, *supra*, § 8.07[5], at 8–276, summary judgment is inappropriate on Bartlett's defective design claims.

V. *Fraud claim*

Mutual also seeks summary judgment on Bartlett's fraud claim (Count 3). "To establish fraud" under New Hampshire law, "a plaintiff must prove that the defendant made a representation with knowledge of its falsity or with conscious indifference to its truth with the intention to cause another to rely upon it," and which actually induces justifiable reliance. *Snierson v. Scruton*, 145 N.H. 73, 77, 761 A.2d 1046 (2000). This showing must be made by clear and convincing evidence. *See, e.g., Burroughs v. Wynn*, 117 N.H. 123, 124, 370 A.2d 642 (1977). On this record, Bartlett has not presented any evidence—much less clear and convincing evidence—of actual reliance on Mutual's allegedly fraudulent misrepresentations. To the contrary, the record shows that neither Bartlett nor her doctor read or relied upon Sulindac's warning label. *See* Part IV, *supra*. Summary judgment is therefore granted to Mutual on Bartlett's fraud claim.

VI. *Enhanced compensatory damages*

Mutual also seeks summary judgment on Bartlett's claim for enhanced compensatory damages. Under

New Hampshire law, punitive damages are prohibited by statute, *see* N.H. Rev. Stat. § 507:16, but an award of compensatory damages may nevertheless be enhanced in "exceptional cases" where the defendant's tortious "act is wanton, malicious, or oppressive." *Stewart v. Bader*, 154 N.H. 75, 87, 907 A.2d 931 (2006). An act is "wanton" if the defendant recklessly creates a risk of great harm. *See Minion, Inc. v. Burdin*, 929 F.Supp. 521, 525 (D.N.H. 1996) (McAuliffe, D.J.) (citing *Thompson v. Forest*, 136 N.H. 215, 220, 614 A.2d 1064 (1992)). An act is "malicious" if the defendant has "ill will, hatred, hostility, or evil motive." *Stewart*, 154 N.H. at 87, 907 A.2d 931. An act is "oppressive" if it constitutes an abuse of power. *See* Walter L. Murphy & Daniel C. Pope, *New Hampshire Civil Jury Instructions* § 9.14, at 9–17 (1996). It is the plaintiff's burden "to present evidence of wanton, malicious or oppressive conduct." *Figlioli v. R.J. Moreau Cos.*, 151 N.H. 618, 622, 866 A.2d 962 (2005).

Bartlett has presented enough evidence, particularly as to wantonness, to avoid summary judgment on this issue. The court cannot say, at least on the current record, that no reasonable jury could conclude that Mutual recklessly created a risk of great harm to consumers like Bartlett. For example, a finding of such recklessness could be based on Mutual's admitted (though explained) failure to survey the medical literature for information about Sulindac's safety risks and its continual manufacture and sale of Sulindac in the face of those risks, even though other drugs were withdrawn from the market based on a similar link to SJS/TEN. Mutual's request for summary judgment on this issue is therefore denied. The scope of Bartlett's claim for enhanced compensatory damages and this court's corresponding

jury instruction will be determined based on the evidence at trial.

Mutual further argues that any award of enhanced compensatory damages must be based solely on its own conduct, not on the severity of Bartlett's injuries. It is true that compensatory damages may be enhanced only if Mutual acted wantonly, maliciously, or oppressively (regardless of what injuries Bartlett suffered). But in analyzing Mutual's conduct, the jury may consider the nature of the risk that Mutual created. *See Stewart*, 154 N.H. at 87, 907 A.2d 931 (citing *Aubert v. Aubert*, 129 N.H. 422, 431, 529 A.2d 909 (1987), and *Kowalski v. Gagne*, 914 F.2d 299, 303 (1st Cir. 1990)). It is undisputed, for example, that Mutual knew Sulindac posed risks on the order of those Bartlett suffered. Moreover, Bartlett's actual injuries are a relevant factor in determining the amount of any enhancement. *See id.* at 88, 907 A.2d 931 (noting that the enhanced compensatory damage award in *Aubert*, 129 N.H. at 431, 529 A.2d 909, "was not excessive in light of the defendant's oppression and ill-will and the plaintiff's 'severe and traumatic' injuries").[11]

VII. *Surveillance of medical literature*

Next, Bartlett seeks summary judgment on the part of her negligence claim (Count 6) which alleges that

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[11] In its reply, Mutual also argues for the first time that an award of enhanced compensatory damages would violate its due process rights under the Fourteenth Amendment to the United States Constitution. This court generally "does not consider theories advanced for the first time in reply" and sees no reason to make an exception here. *Friendfinder*, 540 F. Supp. 2d at 303 (citing L.R. 7.1(e)(1), which restricts reply "to rebuttal of factual and legal arguments raised in the objection").

Mutual breached its duty of care by failing to survey the medical literature for adverse events associated with Sulindac.[12] There is no factual dispute on this issue: Mutual concedes that it did not conduct such surveillance. But the parties disagree over the law. Bartlett argues that FDA regulations required generic manufacturers to survey the medical literature for adverse drug events and that those regulations establish the minimum standard of care under New Hampshire law. Mutual, in contrast, argues that FDA regulations imposed no surveillance requirement on generic manufacturers and, even if they did, only the federal government would have the power to enforce them.

This court already made clear in its earlier pre-emption ruling that 21 C.F.R. § 314.80(b), which requires brand-name drug manufacturers to "develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA," applies equally to generic drug manufacturers by virtue of 21 C.F.R. § 314.98(a), which provides that they too "shall comply with the requirements of § 314.80 regarding the reporting and recordkeeping of adverse drug experiences." *See Bartlett*, 659 F. Supp. 2d at 289, 307; *accord Demahy*, 593 F.3d at 448 ("The FDA also requires that generics 'develop written procedures for the surveillance ... of postmarketing adverse drug experiences to FDA.'") (quoting § 314.80(b)).

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[12] Although this allegation played a more prominent role in Bartlett's failure-to-warn claims (and, to that extent, is moot), it is also relevant to her defective design claims, in that it bears on Mutual's degree of fault, if any, in selling an unreasonably dangerous product. *See* Part VI, *supra*.

Mutual argues that § 314.98(a) makes generic manufacturers subject only to the specific subsections of § 314.80 entitled "Reporting requirements" and "Recordkeeping," *see* 21 C.F.R. § 314.80(c), (i), and not to the surveillance requirement in § 314.80(b), entitled "Review of adverse drug experiences." But the regulations make clear that "*[a]ny person* subject to the reporting requirements under paragraph (c)" of § 314.80 is also subject to the surveillance requirement. *Id.* § 314.80(b) (emphasis added). That language confirms this court's earlier conclusion that the surveillance requirement applies to generic manufacturers.

At oral argument, Mutual suggested that § 314.80(b) only requires manufacturers to develop procedures for collecting reports of specific adverse experiences associated with their own drugs, not for surveying the medical literature for broader safety studies (such as the international study of NSAIDs and SJS/TEN referenced in Part II, *supra*). But the regulation states that manufacturers "shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic," including specifically "reports in the scientific literature" and "postmarketing epidemiological/surveillance studies." 21 C.F.R. § 314.80(b). The most logical interpretation is that those are the same types of sources that manufacturers must develop procedures for surveying.[13]

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[13] Mutual also argues that, under the doctrine of "primary jurisdiction," this court should defer to the FDA for a determination of which regulations apply to generic manufacturers and whether they have been violated. That

The question, then, is whether Mutual's admitted failure to develop safety surveillance procedures as required by federal law constitutes a *per se* violation of its duty of care under New Hampshire law. Unlike most states, New Hampshire generally regards "a causal violation of a statute [as] not merely evidence of fault but [as] legal fault," provided that the plaintiff is a member of the class protected by the statute and the harm is the type against which the statute is designed to protect. 8 Richard B. McNamara, *New Hampshire Practice*, § 4.70, at 4–103 (citing cases). Both of those prerequisites seem to be satisfied here: the FDA's surveillance requirement is designed to protect patients like Bartlett against safety risks like SJS/TEN by ensuring that the drug's warning label reflects up-to-date information.

But the FDA's surveillance requirement is not a statute; it is a safety regulation. The New Hampshire

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doctrine "comes into play whenever enforcement of [a] claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views." *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64, 77 S. Ct. 161, 1 L.Ed.2d 126 (1956). But it was Mutual that initially asked this court to interpret the FDA regulations by moving for judgment on the pleadings based on its pre-emption defense, suggesting, at least, that it regarded the court as competent to resolve these issues. In any event, the interpretation of those regulations is not something for which the judiciary needs the FDA's special competence, as the growing and (so far) uniform body of case law interpreting and applying those regulations indicates. *See, e.g., Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 939 (8th Cir. 2005) ("primary jurisdiction should seldom be invoked unless a factual question requires both expert consideration and uniformity of resolution") (quotation omitted).

Supreme Court has suggested that safety codes generally "are not to be accepted as absolute standards" of care "unless they have been incorporated into statutes or ordinances by either State or local legislative bodies." *Lemery v. O'Shea Dennis, Inc.*, 112 N.H. 199, 200, 291 A.2d 616 (1972). That cautionary language casts serious doubt on whether New Hampshire would treat the violation of a safety regulation as negligence *per se*, particularly a federal regulation which, so far as the record indicates, has not been incorporated into any such statutes or ordinances. *Cf. Mailhot v. C & R Constr. Co.*, 128 N.H. 323, 514 A.2d 1255 (1986) (leaving this issue open in a case involving federal workplace safety regulations).

Another factor that New Hampshire courts consider in determining whether to recognize a negligence *per se* theory is whether doing so would be consistent with the legislative intent as expressed in the relevant law. *See, e.g., Wong v. Ekberg*, 148 N.H. 369, 375, 807 A.2d 1266 (2002); *Marquay v. Eno*, 139 N.H. 708, 716, 662 A.2d 272 (1995). Here, the FDCA expressly provides that "all such proceedings for [its] enforcement ... shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has said that this provision "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n. 4, 121 S. Ct. 1012, 148 L.Ed.2d 854 (2001).

"Because the FDCA does not provide for a private cause of action, many courts have held plaintiffs cannot seek to enforce it through negligence *per se* tort actions." *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002) (citing *Talley v. Danek Med.*,

Inc., 179 F.3d 154, 161 (4th Cir. 1999) and other cases); *see also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000); *Rimbert v. Eli Lilly and Co.*, 577 F. Supp. 2d 1174, 1239–40 (D.N.M. 2008).[14] Other courts, though, have allowed such suits, reasoning that they do not assert private rights of action under the FDCA, but rather a negligence theory long recognized at common law. *See, e.g., In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 788–89 (3d Cir. 1999) (citing cases).

There is no clear answer to this question under New Hampshire law. In such cases, federal courts must make "an informed prophecy of what the [state's highest court] would do in the same situation, seeking guidance in analogous state court decisions, persuasive adjudications by courts of sister states, learned treatises, and public policy considerations." *Walton v. Nalco Chem. Co.*, 272 F.3d 13, 20 (1st Cir. 2001). Based on the sources and considerations discussed above, this court's view is that the New Hampshire Supreme Court would not treat Mutual's violation of 21 C.F.R. § 314.80(b) as establishing a *per se* breach of its duty of care, but rather would allow the jury to consider that violation as evidence of such a breach. *See, e.g., Lemery*, 112 N.H. at 201, 291 A.2d 616 (noting that "standards embodied in safety codes might be of aid to the trial court or the jury on an issue of due care"); 8 McNamara, *supra*, § 4.13, at 4–26 n. 5.[15]

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[14] Indeed, Mutual even argues that doing so would raise federal pre-emption concerns, citing *Buckman*, 531 U.S. at 353, 121 S. Ct. 1012.

[15] In light of this ruling, the court need not decide whether premising a negligence *per se* claim on a violation of FDA regulations amounts to an impermissible private right of action under the FDCA. This court's ruling also avoids the pre-emption

Bartlett's request for summary judgment on this issue is therefore denied.

VIII. *Mutual's affirmative defenses*

Next, Bartlett seeks summary judgment on two of Mutual's affirmative defenses: (1) set-off and (2) spoliation.[16] Both defenses were originally stricken by this court in its discovery order following the preliminary pre-trial conference in October 2008, "without prejudice to being reinstated on request if warranted by the evidence."[17] Mutual, without making any evidentiary showing, reinstated both defenses in the answer to Bartlett's amended complaint that it filed in February 2010. Bartlett argues that neither Mutual's answer nor its summary judgment objection amounts to a formal request for reinstatement. But even construing them as such, this court sees no basis for reinstating either defense.

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concerns raised by Mutual. *See Buckman*, 531 U.S. at 352–53, 121 S. Ct. 1012 (allowing state-law claims to "parallel federal safety requirements" where they arise "from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements").

[16] Bartlett initially challenged a large number of defenses, but Mutual conceded that some of them should be stricken (i.e., standing, unclean hands, laches, waiver, estoppel, statute of limitations, and excessive delay), and Bartlett withdrew some of her other challenges in her reply brief. She also withdrew one at oral argument (failure to mitigate). Another defense that she challenged (product modification) is moot in light of this court's ruling that Mutual is entitled to summary judgment on Bartlett's failure-to-warn claims, *see* Part IV, *supra*, since the defense was based on the pharmacy's decision to give Bartlett a pharmacy-created "prescription adviser" instead of Mutual's safety warning.

[17] Document no. 24.

A. *Set-off*

According to Mutual, its "set-off" defense is based on its argument that fault should be apportioned to a third party, Dr. Ergin, or to Bartlett herself under New Hampshire's apportionment statute, N.H. Rev. Stat. § 507:7–e. But "set-off" is not the correct label for that defense. *See, e.g., In re Liquidation of Home Ins. Co.*, 158 N.H. 677, 680, 972 A.2d 1019 (2009) ("Setoff allows entities that owe each other money to apply their mutual debts against each other, thereby avoiding the absurdity of making A pay B when B owes A.") (quotation omitted). Moreover, Mutual has already asserted a specific apportionment defense, which Bartlett has not challenged, seeking reduction of its liability based on the conduct of third parties. In light of that defense, there is no need to reinstate Mutual's mislabeled set-off defense.

B. *Spoliation*

The spoliation defense is based on the fact that Mutual has never been allowed to inspect Bartlett's original Sulindac container and unused pills. But the transcript from Bartlett's deposition in May 2009 shows that the parties arranged for Mutual's counsel to contact Bartlett's counsel afterward to arrange such an inspection. That appears never to have happened. Bartlett recently sent Mutual pictures of the container and pills and confirmed her willingness to arrange an inspection in advance of trial. If Mutual still wishes to conduct the inspection, it may do so by accepting one of the reasonable options offered by Bartlett's counsel.

Based on the pictures that Bartlett provided, Mutual also argues that the number of unused Sulindac pills (15 out of the original 60) is inconsistent with Bartlett's testimony about how many pills she

took (40), thus indicating either that she took too many pills or that some pills were destroyed. But that discrepancy alone is not enough to warrant reinstatement of Mutual's spoliation defense, at least on the current record. Spoliation occurs where a party culpably destroys relevant evidence in her possession while under a duty to preserve it. *See N.H. Ball Bearings, Inc. v. Jackson*, 158 N.H. 421, 434, 969 A.2d 351 (2009). Mutual has not identified any evidence that Bartlett, who was in a coma for months after developing SJS/TEN, culpably destroyed pills while anticipating litigation.[18]

IX. *Pre-emption redux*

Finally, Mutual asks this court to revisit its earlier preemption ruling in light of the deposition testimony of three former FDA officials, each of whom testified that the FDA's policy is to prohibit manufacturers from unilaterally strengthening a generic drug's label. *See Bartlett*, 659 F. Supp. 2d at 279 (ruling that federal law allows such changes). But as Mutual concedes, those officials "were not deposed to offer opinions or interpretations of federal statutes or regulations." Their testimony thus has little, if any, relevance to the preemption issue and, indeed, plays a minimal role in Mutual's arguments in support of its motion. *Cf. Rose v. Chase Bank USA, N.A.*, 513 F.3d 1032, 1038 n. 4 (9th Cir. 2008) (noting that "no amount of discovery"

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[18] Of course, this is a pretrial ruling based on a summary judgment record. Nothing prevents Mutual from using the number of pills remaining to challenge Bartlett's testimony about the number of pills she took. If her testimony suggests culpable destruction, then Mutual may request that this court reconsider whether to give a spoliation instruction. *See, e.g., Testa v. Wal-Mart Stores, Inc.*, 144 F.3d 173, 177 (1st Cir. 1998).

would change the court's pre-emption ruling, which was based on congressional intent).

Although presented in the guise of a summary judgment motion, Mutual's argument is really one for reconsideration of the court's earlier ruling. *See Rodriguez–Antuna v. Chase Manhattan Bank Corp.*, 871 F.2d 1, 2 (1st Cir. 1989) ("a motion which asks the court to modify its earlier disposition ... solely because of an ostensibly erroneous legal result" is a motion for reconsideration). This court will therefore analyze it as such. A motion for reconsideration must "demonstrate that the order [being challenged] was based on a manifest error of fact or law" and must be filed within 14 days of the order, unless the party shows cause for not filing it within that time. L.R. 7.2(e). Here, Mutual filed its motion about six months after this court's earlier ruling, long after the 14–day deadline.

Mutual seems to be suggesting that the depositions of former FDA officials constitute "newly available material evidence," which can be cause for a late filing under Local Rule 7.2(e). But as explained above, such evidence is not material or even relevant to the pre-emption issue. Nor is it truly "new." Mutual admitted at oral argument that at least two of the officials had testified many times in other cases and that it anticipated what they would say when deposed here. And even if the evidence were new and material, Mutual unreasonably delayed in filing its motion. One of the depositions took place less than a month after this court's earlier ruling, and even the most recent one occurred more than two months before Mutual's motion. This court therefore denies Mutual's motion for reconsideration as untimely.

Even if it were timely, Mutual's motion for reconsideration would still be denied because Mutual has not identified "a manifest error of fact or law" in this court's earlier ruling, which analyzed the relevant statutes and regulations in painstaking detail. Since that ruling, two federal circuit courts have reached the same conclusion that this court reached, based on substantially the same reasoning. *See Demahy*, 593 F.3d at 428; *Mensing*, 588 F.3d at 603. While generic drug manufacturers (including Mutual) continue to refine and adapt their arguments in response to those unsuccessful outcomes, this court is not persuaded that those refinements change the fundamental analysis or the outcome.[19]

X. *Conclusion*

Mutual's motion for summary judgment[20] is GRANTED as to Bartlett's claims of strict products liability (Count 1) and negligence (Count 6) based on failure to warn, as well as her claim of fraud (Count 3), but is DENIED as to her claims of strict products liability (Count 2) and negligence (Count 6) based on defective design, as well as her request for enhanced compensatory damages. Mutual's separate motion for summary judgment based on federal pre-emption,[21] which is actually a motion for reconsideration of this court's earlier pre-emption ruling, is also DENIED. Bartlett's motion for partial summary judgment[22] is

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[19] Since this court's pre-emption ruling remains in effect, Bartlett's competing request for summary judgment on issues relating to pre-emption is moot.

[20] Document no. 146.

[21] Document no. 145.

[22] Document no. 131.

GRANTED as to Mutual's set-off and spoliation defenses, but is otherwise DENIED.

SO ORDERED.

United States District Court, D. New Hampshire

KAREN L. BARTLETT,

and

GREGORY S. BARTLETT,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC., et al.

Civil No. 08-cv-358-JL

September 30, 2009

ORDER

JOSEPH N. LAPLANTE, District Judge.

This case presents a question currently pending before three different federal courts of appeal: whether state-law tort claims alleging the defective labeling of generic drugs are preempted by federal law. *See Morris v. Wyeth, Inc.*, No. 09–5509 (6th Cir. Apr. 27, 2009); *Demahy v. Wyeth, Inc.*, No. 08–31204 (5th Cir. Dec. 16, 2008); *Mensing v. Wyeth, Inc.*, No. 08–3850 (8th Cir. Dec. 10, 2008). The defendants, Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc., move for judgment on the pleadings, *see* Fed. R. Civ. P. 12(c), on claims by the plaintiffs, Karen L. and Gregory S. Bartlett, alleging that Karen suffered serious injuries from Sulindac, a generic drug manufactured by the defendants. The defendants argue that all of the plaintiffs' state-law causes of

action are pre-empted by Title I of the Drug Price Competition and Patent Term Restoration Act of 1984,[1] part of the Hatch–Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA").[2] This court has subject-matter jurisdiction under 28 U.S.C. § 1332(a)(1) (diversity).

After considering the parties' extensive briefing and oral argument, the court denies the defendants' motion for judgment on the pleadings. The Bartletts' claims do not present an obstacle to the accomplishment and execution of the full purposes and objectives of Congress in the Hatch–Waxman Amendments, nor does complying with the state law underlying those claims make it impossible to comply with the Hatch–Waxman Amendments or any other federal law identified by the defendants. The Supreme Court's recent decision on the pre-emptive effect of federal drug regulation on state tort law in *Wyeth v. Levine*, 555U.S. 555, 129 S. Ct. 1187, 173 L.Ed.2d 51 (2009), makes that result clear. Accordingly, the Bartletts' claims are not pre-empted.

I. *Applicable legal standard*

Federal "preemption is an affirmative defense on which [the] defendant bears the burden of proof." *Cambridge Literary Props., Ltd. v. W. Goebel Porzellanfabrik G.m.b.H. & Co. KG.*, 510 F.3d 77, 102 (1st Cir. 2007), *cert. denied*, 555 U.S. 815, 129 S. Ct. 58, 172 L.Ed.2d 25 (2008); *see also Wyeth*, 129 S. Ct. at 1193 (characterizing a manufacturer's argument that

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[1] Pub. L. 98–417, tit. I, 98 Stat. 1985, *codified as amended* at 21 U.S.C. § 355(j) (1999 & supp. 2009)

[2] Ch. 675, 52 Stat. 1040 (1938), *codified as amended at* 21 U.S.C. §§ 301 *et seq.* (1999 & supp.2009).

federal drug law pre-empted the plaintiff's claims as a defense). While an affirmative defense can support a Rule 12(c) motion for judgment on the pleadings, it can do so "only where it is (1) definitively ascertainable from the complaint and other sources of information that are reviewable at [the pleadings] stage, and (2) [these] facts establish the affirmative defense with certitude." *Citibank Global Mkts., Inc. v. Rodriguez Santana*, 573 F.3d 17, 23 (1st Cir. 2009).

II. *Background*

A. The Bartletts' allegations

For purposes of the defendants' motion for judgment on the pleadings, the court accepts the following allegations of the Bartletts' complaint as true. *See Gray v. Evercore Restructuring L.L.C.*, 544 F.3d 320, 324 (1st Cir. 2008). In December 2004, Karen Bartlett's physician prescribed her Sulindac, a non-steroidal anti-inflammatory drug manufactured by the defendants, for pain in her right shoulder. Within weeks of filling the prescription, she went to a local emergency room complaining of "pimple like bumps, spots or blisters on her face, a fever, eye irritation," and other symptoms. She was soon diagnosed with Stevens–Johnson syndrome progressing to toxic epidermal necrolysis, a serious and potentially fatal condition characterized by large areas of lesions on and necrosis of the skin and mucous membranes. *See Dorland's Illustrated Medical Dictionary* 1872 (31st ed. 2007). She spent approximately three months in the hospital recovering, including two months in a medically induced coma, and emerged with permanent injuries.

Sulindac is the generic version of a drug originally approved by the FDA in 1978; the generic version at

issue here was approved in 1991. The Bartletts allege that, following this approval, the defendants "had an ongoing duty to conduct postmarketing safety surveillance for any reports of serious adverse events associated with Sulindac including any such report in the medical literature" and that, had they done so, they would have uncovered information compelling them "to warn physicians about the dangers" of the drug, including associations with Stevens–Johnson syndrome and toxic epidermal necrolysis.

The Bartletts' complaint asserts seven counts:

- strict product liability—failure to warn (count 1);
- strict product liability—defective in design or manufacture (count 2);
- fraud, in the sense that the defendants "made misrepresentations of material facts ... and omitted and/or concealed material facts" about the risks of Sulindac (count 3);
- breach of implied warranty that Sulindac was "of merchantable quality and safe and fit for [its intended] use" (count 4);
- breach of express warranty that Sulindac "was safe and well accepted by patients and was safe for long-term use" (count 5);
- negligence in failing "to use reasonable care in designing, testing, labeling, marketing, supplying, distribution *[sic]* and selling" Sulindac (count 6);
- gross negligence based on the same omissions (count 7).

B. The statutory and regulatory scheme

1. Overview of the FDA approval process

The FDCA prohibits the "introduction into interstate commerce [of] any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."[3] 21 U.S.C. § 355(a). As discussed in detail below, those two subsections provide two different procedures for obtaining the requisite approval from the Secretary of Health and Human Services to distribute a new drug. The Secretary oversees the Food and Drug Agency in carrying out these procedures. *See id.* § 393(b)(2)(A).

Subsection (b) authorizes a new drug application ("NDA") containing certain specified data, e.g., "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective for use," "a full list of the articles used as components of such drug," and "specimens of the labeling proposed to be used for such drug." *Id.* § 355(b)(1). The Secretary shall approve such an application absent specified grounds for denial. *See id.* § 355(c)(1)(A). These grounds include, e.g., that the required investigations "do not include adequate tests ... to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," that "results of such tests show that such drug is unsafe for

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[3] The FDCA defines "new drug," in relevant part, as "[a]ny drug ... the composition of which is such that such drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1).

use under such conditions," and that "based on a fair evaluation of all material facts, such labeling is unsafe or misleading in any particular." *Id.* § 355(d).

Subsection (j), the Hatch–Waxman Amendments, sets forth a process under which "[a]ny person may file with the Secretary [of HHS] an *abbreviated* application for the approval of a new drug." *Id.* § 355(j)(1) (emphasis added). Rather than the data required of a full-blown NDA by subsection (b), an abbreviated application ("ANDA") must show that "the conditions of use prescribed, recommended, or suggested in the labeling have been previously approved for ... a listed drug," *id.* §§ 355(j)(2)(A)(i) (internal quotation marks and parentheses omitted), and that each of a number of specified characteristics of the new drug is "the same as that of the listed drug." *Id.* §§ 355(j)(2)(A)(ii)-(v). These characteristics include the drug's active ingredient, route of administration, dosage form, strength, and labeling. *See id.*

A "listed drug" is a "drug which has been approved for safety and effectiveness under subsection (c) of this section," *id.* § 355(j)(7)(A)(i)(I), which, as just discussed, governs the approval of applications submitted under subsection (b). The Secretary must approve an ANDA absent certain specified grounds, e.g., "information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug," *id.* § 355(j)(4)(B), or "information submitted in the application is insufficient to show that the labeling

proposed for the drug is the same as the labeling approved for the listed drug,"[4] *id.* § 355(j)(4)(G).

The Hatch–Waxman Amendments, then, authorize the approval of a new drug without demanding the information that would otherwise be required in an application under subsection (b), i.e., the reports of safety and effectiveness investigations and the like, provided the same drug has been previously approved for the same conditions under that more rigorous process. As one committee report on the Amendments noted, their "focus ... is to provide the Food and Drug Administration with sufficient information to assure that the generic drug is the same as the listed drug that has previously been determined to be safe and effective." H.R. Rep. No. 98–857, pt. 1, at 21 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2654 (footnote and parenthetical omitted). The term "generic drug," in this context, refers to a "listed drug" not covered by a patent, whether because that patent has expired or otherwise. *See* 21 U.S.C. § 355(j)(2)(A)(vii).

2. ANDA procedures before Hatch–Waxman

As this committee report also noted, the FDA had, at that point, already been approving ANDAs for generic drugs, but only insofar as such a drug was "the same as [a] pioneer [i.e., non-generic] drug" approved prior to 1962. H.R. Rep. No. 98–857, pt. 1, at 16, 1984 U.S.C.C.A.N. at 2649; *see also* Abbreviated New Drug Applications, 48 Fed. Reg. 2751, 2755 (Jan. 21, 1983) *(later codified* at 21 C.F.R. § 314.2 (1984)). This

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[4] There is an exception to this requirement "for changes required because of differences approved under a petition filed under [21 U.S.C. § 355(j)(2)(C)] or because the new drug and the listed drug are produced or distributed by different manufacturers." 21 U.S.C. § 355(j)(2)(A)(v). That exception is not at issue in this case.

temporal limitation had its origins in the Drug Amendments of 1962, which "required that all drugs, both generic and pioneer, ... be approved as safe and effective [by the FDA] prior to marketing"; before those amendments, the FDA had approved drugs on the basis of safety alone. H.R. Rep. No. 98–857, pt. 1, at 16, 1984 U.S.C.C.A.N. at 2649; *see also* Drug Amendments of 1962 §§ 102(d) *(codified as amended* at 21 U.S.C. § 355(d)).

To carry out the mandate of the Drug Amendments, the FDA "created the drug efficacy study (DESI) to determine if all pre–1962 [approved] drugs were effective." H.R. Rep. No. 98–857, pt. 1, at 16, 1984 U.S.C.C.A.N. 2647, 2649. The FDA later concluded that the reports generated in that study, together with other available data, "constituted a body of information sufficient, in the case of most DESI drugs determined to be effective, to conclude that the same drug product produced by another manufacturer would also be safe and effective if properly manufactured and used under the same conditions." Abbreviated Drug Applications, 43 Fed. Reg. 39126, 39127 (proposed Sept. 1, 1978). Thus, the FDA promulgated a rule allowing an ANDA for a particular new drug upon a finding that such an approach was "sufficient." Abbreviated Applications, 35 Fed. Reg. 6574, 6575 (Apr. 24, 1970) *(later codified* at 21 C.F.R. § 130.4 (1971)). This rule required, in relevant part, that an ANDA contain "[l]abeling that is in accord with the labeling conditions described in the finding." *Id. (later codified* at 21 C.F.R. § 130.4(f)(2) (1971)).

After receiving ANDAs for new drugs varying from ones approved through the DESI program in ways that "pose[d] significant questions of safety or

effectiveness," however, the FDA proposed a new rule limiting the ANDA process. 43 Fed. Reg. at 39127. This rule, promulgated in 1983, permitted an ANDA only upon a finding that a drug product "covered by [DESI] may be approved for marketing without the submission of additional evidence of preclinical and clinical studies to show safety and effectiveness." 48 Fed. Reg. at 2755 (parenthetical omitted) *(later codified* at 21 C.F.R. § 314.2(a) (1984)).

The new rule also provided that such a finding, i.e., "that an [ANDA] is suitable for a drug product[,] applies only to a product that is the same in active ingredient, dosage form and strength, route of administration, and conditions of use as the drug product that was the subject of the finding." *Id. (later codified* at 21 C.F.R. § 314.2(b)(2)). This amendment did not alter the requirement that an ANDA contain "[l]abeling that is in accord with the labeling conditions described in the finding that an [ANDA] is sufficient." *Id.* at 2756 *(later codified* at 21 C.F.R. § 314.2(f)(2)).

At the time it proposed this rule, the FDA announced its "inten[t] to extend the ANDA concept at a later time to post–1962 drug products by publishing criteria for making a determination about these drugs," noting that the rationale for the ANDA concept covered drugs approved before 1962 only—since only they had been subjected to the rigors of the DESI process. 43 Fed. Reg. at 39128. The FDA never did act on its own to make the ANDA process available for drugs approved after 1962, H.R. Rep. No. 98–857, pt. 1, at 16, 1984 U.S.C.C.A.N. at 2649, so Congress acted through the Hatch–Waxman Amendments, "generally extend[ing] the procedures used to approve generic

copies of pre–62 drugs to post–62 drugs," *id.*, at 14, 1984 U.S.C.C.A.N. at 2647.

Doing so, the committee report recognized, would allow the FDA to approve such drugs without requiring human clinical trials, "retesting" which the FDA saw as "unnecessary and wasteful"—as well as "unethical"—"because the drug has already been determined to be safe and effective." *Id.* at 16, 1984 U.S.C.C.A.N. at 2649. The committee report also noted that the "approximately 150 drugs approved after 1962 that [were] off patent and for which there [was] no generic equivalent" at that time "could be approved in generic form if there was [an ANDA] procedure," resulting in significant cost savings. *Id.* at 17, 1984 U.S.S.C.A.N. at 2650.

3. ANDA procedures after Hatch–Waxman

The FDA later proposed amending its regulations to implement the ANDA procedure set forth in the Hatch–Waxman Amendments. *See* Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28872 (proposed July 10, 1989). In relevant part, the FDA proposed "to *add a new requirement* with respect to the submission of labeling as part of an ANDA" to effect Hatch–Waxman's rule that an ANDA "show that the proposed labeling for its drug product is the same as that of the reference listed drug." *Id.* at 28884 (emphasis added). The FDA then promulgated rules specifying that an ANDA must include "[a] statement that the applicant's proposed labeling is the same as the labeling of the reference listed drug except for" enumerated differences not relevant here. Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17950, 17985–86 (Apr. 28, 1992) (*later codified* at 21 C.F.R. §§ 314.94(a)(8)(iii)-(iv) (1993)).

These rules also stated that the FDA would deny an ANDA if it was "insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug," *id.* at 17992 (later codified at 21 C.F.R. § 314.127(a)(7) (1993)), and that the FDA "may" begin proceedings to withdraw its approval of an ANDA if it found "*[t]hat the labeling for the drug product that is the subject of the [ANDA] is no longer consistent with that for the listed drug*," *id.* at 17993–94 (*later codified* at 21 C.F.R. § 314.150(b)(10) (1993)) (emphasis added), both with exceptions not relevant here.[5]

During the notice-and-comment period on these rules, the FDA received feedback that "the labeling provisions should be revised to permit ANDA applicants to deviate from the labeling for the reference listed drug to add contraindications, warnings, precautions, adverse reactions, and other safety-related information." *Id.* at 17961. The FDA noted that it "disagree[d].... [T]he ANDA's product labeling must be the same as the listed drug's product labeling because the listed drug product is the basis for ANDA approval." *Id.* But the FDA also noted that

> Consistent labeling will assure physicians, health professionals, and consumers that a generic drug is as safe and effective as its brand-name counterpart. If an ANDA

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[5] Though the FDA has since made slight modifications to § 314.94, *see* Prescription Drug Product Labeling; Medication Guide Requirements, 63 Fed. Reg. 66378–01, 66397 (Dec. 1, 1998), these are in relevant part the same regulations that were in effect at the time Karen Bartlett was prescribed and ingested Sulindac, and that remain in effect today. *See* 21 C.F.R. §§ 314.94(a)(8)(iv), 314.127(a)(7), 314.150(b)(10) (2008).

> applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. *After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.*

Id. (emphasis added).

Further, in response to a comment that "FDA should create a mechanism to compel ANDA holders to revise their labeling to conform to the listed drug product once the ANDA is approved," the FDA observed that 21 U.S.C. § 355(e)(2)

> authorizes the withdrawal of approval of an application if 'there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.' This provision applies to both ANDA and NDA drug products. Because an ANDA must have labeling that is the same as the reference listed drug under [21 U.S.C. § 355(j)(2)(A)(v)], FDA believes that a generic drug product approved on the basis of studies conducted on the listed drug and *whose labeling is inconsistent with the listed drug's labeling* might not be considered safe and effective for use under the conditions prescribed, suggested, or recommended in the listed drug's

> labeling. FDA, therefore, *has revised § 314.150 to permit the agency to withdraw approval of the ANDA if the applicant fails to maintain labeling in compliance with the requirements of the Act.*

Id. at 17968 (emphases added). In explaining this revision, the FDA noted its agreement with comments that it "should create a new provision authorizing the agency to withdraw an [ANDA] if the [ANDA] holder failed to modify its labeling to match labeling changes in the reference listed drug."[6] *Id.* at 17970. Thus, the FDA explained, "§ 314.150(b)(10) states that the ANDA applicant's failure to maintain drug labeling that is consistent with that of the listed drug may be grounds for withdrawing approval of the [ANDA]." *Id.* (emphasis added).

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[6] The FDA had initially proposed to "retain its current regulations under § 314.150 stating the grounds for the withdrawal of approval of applications and abbreviated applications for drugs under [21 U.S.C. § 355(e)]," while adding regulations "to describe additional circumstances under which the agency will suspend or withdraw ANDA approval under [21 U.S.C. § 355(j)(5)]." 54 Fed. Reg. at 28904. Section 355(j)(5), in essence, directs the Secretary to withdraw or suspend an ANDA upon the withdrawal or suspension of its listed drug's application; those were the "additional circumstances" described in the added regulations. 54 Fed. Reg. at 17993 *(codified at* 21 C.F.R. §§ 314.151, 314.153 (2008)).

4. Revisions to drug labeling

Revisions to drug labeling are covered under another FDA regulation, 21 C.F.R. § 314.70, "Supplements and other changes to an approved application." Under this rule, before making "[c]hanges in labeling," *id.* § 314.70(b)(2)(v)(A), the applicant must submit, and the FDA must approve, a "supplement" describing the change, *id.* §§ 314.70(a)(1)(i), (b)(1). The rule has exceptions, however, *see id.* § 314.70(b)(2)(v)(A), one of which is for "[c]hanges in the labeling ... [t]o add or strengthen a contraindication, warning, precaution, or adverse reaction," *id.* § 314.70(c)(6)(iii)(A). In such a case, "the holder of an approved application may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change," rather than waiting for the FDA to approve it. *Id.* § 314.70(c)(6)(iii). This is known as a "changes being effected" or "CBE" supplement. *Id.* § 314.70(c)(3). As with other changes in labeling, the FDA may ultimately disapprove a change made through the CBE process, in which case "it may order the manufacturer to cease distribution of the drug product(s) made with the ... change." *Id.* § 314.70(c)(7).

This version of the rule was promulgated in 2004, following the passage of Food and Drug Administration Modernization Act of 1997 ("FDAMA").[7] Supplements and Other Changes to an Approved Application, 69 Fed. Reg. 18728, 18764–65 (Apr. 8, 2004).[8] The

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[7] Pub.L. 105–115, § 116(a), 111 Stat. 2296, 2313 (*codified* at 21 U.S.C. § 356a (1999)).

[8] The rule was subsequently revised in ways not relevant here. Requirements on Content and Format of Labeling for Human

Modernization Act provided that, "[w]ith respect to a drug for which there is in effect an approved application under section 355 ..., a change from the manufacturing process approved pursuant to such an application ... may be made, and the drug as made with the change may be distributed." 21 U.S.C. § 356a(a). The Act authorized the Secretary to "designate a category of ... changes for the purpose of providing that ... the holder involved may commence distribution of the drug involved upon the receipt by the Secretary of a supplemental application for the change," rather than wait for approval. *Id.* § 356a(d)(3)(B)(ii).

So, by opening the CBE process to labeling changes that added or strengthened warnings and the like under 21 C.F.R. § 314.70(c)(6)(iii)(A), the Secretary created "a category of changes" that could be implemented upon receipt of a supplemental application effecting them. In substance, however, a rule like § 314.70(c)(6)(iii)(A) had been in effect since 1965, when the Secretary promulgated a rule that, if a supplemental application proposed "additional warning, contraindication, side-effect, [or] precaution information" to package labeling, that change "should be placed in effect at the earliest possible time." Supplemental New–Drug Applications. 30 Fed. Reg. 911, 993 (Jan. 30, 1965) *(later codified at* 21 C.F.R. § 130.9(d)(1) (1965)). To effect this goal, the FDA announced in the rule a policy "to take no action against a drug or applicant solely because changes of [this] kind ... are placed in effect by the applicant prior to his receipt of a written notice of approval." *Id.* at 994 (*later codified at* 21 C.F.R. § 130.9(e)).

Prescription Drugs and Biological Products, 71 Fed. Reg. 3922, 3997 (Jan. 24, 2006).

Despite some renumbering, *see* 39 Fed. Reg. 11680, 117123 (Mar. 29, 1974) (recodifying § 130.9 as § 314.8), the relevant substance of this rule remained the same until 1985, when the rule took its current form. *See* New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452, 7498–99 (Feb. 22, 1985) (*later codified at* 21 C.F.R. § 314.70 (1985)). Though the Hatch–Waxman Amendments had already become law at that point, the FDA had yet to promulgate the regulations implementing them; when the agency did so, however, the only change it made to the rule on supplemental applications, § 314.70, was to add a paragraph directing that "[t]he applicant shall comply with the patent information requirements under section 505(c)(2) of the act."[9] Abbreviated New Drug Applications, 57 Fed. Reg. at 17983 (*codified at* 21 C.F.R. § 314.70(f)).

But later, in a 2008 proposal to amend 21 C.F.R. § 314.70(c) "to reaffirm that a CBE supplement is appropriate to amend the labeling for an approved product only to reflect newly acquired information," the FDA stated in a footnote that "CBE changes are not available for generic drugs approved under an [ANDA] under 21 U.S.C. [§] 355(j). To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug." Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg.

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[9] When FDA amended the rule again in response to the Modernization Act, its only substantive edit to the CBE provision, § 314.70(c)(6), was to allow distribution of the revised drug product "upon receipt by the agency of the supplement for the change," rather than "promptly" as under the former rule. *Compare* 69 Fed. at 18764–65 *with* 50 Fed. Reg. at 7498–99.

2848–01, 2849 n. 1. (proposed Jan. 16, 2008). The footnote cited 21 C.F.R. § 314.150(b)(10)—which provides, again, that the FDA may attempt to revoke its approval of an ANDA if its labeling is not "consistent with" that of the listed drug—as well as the FDA's comments on ANDA applicants' labels, quoted above.

The FDA did not, however, propose to amend any of its regulations to clarify that an ANDA holder could not avail itself of a CBE supplement. *See id.* Nor did its final version of the proposed rule contain any such provision. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603–01 (Aug. 22, 2008). And the footnote in the proposal did not acknowledge that, when the FDA promulgated its new rule on ANDA applications following Hatch–Waxman, it included a provision that "[t]he applicant shall comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications to an approved abbreviated application."[10] 57 Fed. Reg. at 17987 (*codified at* 21 C.F.R. § 314.97).

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[10] 21 C.F.R. § 314.71 sets forth the procedures for submitting a supplement to an application.

5. Generic manufacturers' reporting obligations

The ANDA regulations promulgated after Hatch–Waxman require that "each applicant having an [ANDA] ... shall comply with the requirements of § 314.80 regarding the reporting and recordkeeping of adverse drug experiences." *Id.* at 17983 (*codified as amended at* 21 C.F.R. § 314.98(a)). Section 314.80 requires an applicant to report (A) "each adverse drug experience that is both serious and unexpected ... as soon as possible but in no case later than 15 calendar days of the initial receipt of the information by the applicant," 21 C.F.R. § 314.80(c)(1)(i), and (B) every other "adverse drug experience ... at quarterly intervals, for 3 years from the date of approval ... and then at annual intervals," *id.* § 314.80(c)(2)(i).[11] Furthermore, an applicant "shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA." *Id.* § 314.80(b).

Congress also addressed the ongoing responsibilities of generic drug manufacturers in the Food and Drug Administration Amendments Act of 2007.[12] This law requires the Secretary to "promptly notify the responsible person"—defined as the holder of an application for a prescription drug approved under subsection (b), *see* 21 U.S.C. § 355(o)(2)—"or, if the same drug approved under subsection (b) of this

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[11] Periodic reporting "does not apply to adverse drug experience information obtained from postmarketing studies," 21 C.F.R. § 314.80(c)(2)(iii), nor need such information be included in a "15–day Alert report ... unless the applicant concludes there is a reasonable possibility that the drug caused the adverse experience," *id.* § 314.80(e)(1).

[12] Pub.L. 110–85 § 107, 121 Stat. 823, 841.

section is not currently marketed, the holder of an approved application under subsection (j)," "if the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug." 21 U.S.C. § 355(o)(4). The holder of the ANDA approval must, in response, either "submit a supplement proposing changes to the approved labeling to reflect the new safety information" or explain "why such a change is not warranted." *Id.* §§ 355(o)(4)(B)(i), (ii).

Paragraph (4) of subsection (*o*) also contains a "Rule of construction" that it "shall not be construed to affect the responsibility of ... the holder of the approved application under [21 U.S.C. § 355(j)] to maintain its label in accordance with existing requirements, including subpart B of part 201 and section[ ] 314.70 ... of Title 21, Code of Federal Regulations (or any successor regulations)." *Id.* § 355(o)(4)(I). Subpart B of part 201 imposes labeling requirements on prescription drugs, including that "[t]he labeling shall be revised to include a warning as soon as there is reasonable evidence of a serious hazard with a drug; a causal relationship need not have been proved."[13] 21 C.F.R. § 201.80(e) (2008).

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[13] As the result of a 2006 amendment to these rules, "[p]rescription drug products for which a new drug application (NDA), biologics license application (BLA), or efficacy supplement was approved ... between June 30, 2001 and June 30, 2006," or which was pending or submitted on or after that date, are subject to "Labeling requirements for new and more recently approved prescription drug products" set forth at 21 C.F.R. §§ 201.56(d) and 201.57. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3986–87 (Jan. 24, 2006) (*codified at* 21 C.F.R. § 201.56(b)(1), (d) (2008)). But "[p]rescription drug products not described in

II. *Analysis*

The defendants argue that all of the Bartletts' claims are pre-empted by the Hatch–Waxman Amendments to the FDCA or the ANDA regulations that followed it. "A fundamental tenet of our federalist system is that constitutionally enacted federal law is supreme to state law. *See* U.S. Const. Art. VI. cl. 2. As a result, federal law sometimes preempts state law either expressly or by implication." *N.H. Motor Transp. Ass'n v. Rowe*, 448 F.3d 66, 74 (1st Cir. 2006), *aff'd*, 552 U.S. 364, 128 S. Ct. 989, 169 L.Ed.2d 933 (2008).

The defendants make no express preemption argument here; indeed, nothing in the Hatch–Waxman Amendments expressly preempts state law.[14] Instead,

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paragraph (b)(1) of this section"—i.e., other than for which an NDA, BLA, or efficacy supplement was approved after June 30, 2001—"are subject to the labeling requirements" set forth at 21 C.F.R. §§ 201.56(e) and 201.80. *Id.* at 3987 *(codified at* 21 C.F.R. § 201.56(b)(2) (2008)). The version of these rules previously in effect, including when Karen Bartlett was prescribed and ingested Sulindac, contained the same requirement as the 2008 version of § 210.80(e). *See* Labeling and Prescription Drug Advertising; Content and Format for Labeling for Prescription Human Drugs, 44 Fed. Reg. 37434, 37463 (June 26, 1979) *(later codified at* 21 C.F.R. § 201.57(e) (1980)). As the FDA explained in enacting the 2008 version of the labeling rules, "older drugs not subject to the revised labeling content and format requirements in § 201.57 remain subject to labeling requirements at former § 201.57, which is redesignated as § 201.80." 71 Fed. Reg. at 3965.

[14] As the Bartletts point out, when Congress previously amended the FDCA, in 1962, it included a provision that "[n]othing in the amendments ... shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962, Pub. L. 87–781, § 201, 76 Stat. 780, 793.

the defendants argue for implicit preemption of the Bartletts' state-law claims. "[F]ederal law can preempt state law by implication in two ways," as the court of appeals has explained:

> First, Congress may indicate an intent to occupy an entire field to the exclusion of state law. Second, even if Congress has not occupied the field, state law is nevertheless pre-empted to the extent it actually conflicts with federal law, that is, when compliance with both state and federal law is impossible, or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Good v. Altria Group, Inc., 501 F.3d 29, 47 (1st Cir. 2007) (internal quotation marks and citations omitted), *aff'd*, 555 U.S. 70, 129 S. Ct. 538, 172 L.Ed.2d 398 (2008). The defendants also make no "field preemption argument," relying solely on "conflict preemption" instead.

The defendants invoke both kinds of conflict pre-emption, though: that complying with the state law underlying the Bartletts' claims (1) would be

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But this provision, by its terms, applies only to the 1962 amendments (none of which is at issue here) and therefore does not on its face limit the pre-emptive effect—if any—of other provisions of the FDCA, such as the Hatch–Waxman Amendments. Nevertheless, the Supreme Court has viewed this provision as one indicator among many that "Congress took care to preserve state law" while enlarging federal oversight of prescription drugs. *Wyeth*, 129 S. Ct. at 1195–96 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S. Ct. 999, 1017, 169 L.Ed.2d 892 (2008) (Ginsburg, J., dissenting)). As discussed *infra*, that observation does bear upon the pre-emption question here, as it did in *Wyeth*.

impossible in light of, and (2) would frustrate the goals of, the Hatch–Waxman Amendments and the subsequent ANDA regulations. Specifically, the defendants argue that, having obtained FDA approval for their generic version of Sulindac under the ANDA procedure envisioned by Hatch–Waxman, they could not change Sulindac's design, or the warnings included in the drug's labeling, without running afoul of federal law (impossibility pre-emption). They further argue that, even if the FDA could approve such a change, it could come only after "substantial expense to obtain the scientific substantiation necessary to support [it]," frustrating Hatch–Waxman's goal to "increase the availability of low-cost generic drugs" by opening the ANDA process to them (frustration-of-purpose pre-emption).

As the Supreme Court reaffirmed in *Wyeth*, " 'the purpose of Congress is the ultimate touchstone in every pre-emption case.'" 129 S. Ct. at 1194 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L.Ed.2d 700 (1996) (further internal quotation marks omitted by the Court)). The Court also reaffirmed in *Wyeth* that " '[i]n all preemption cases, and particularly in those in which Congress has legislated ... in a field which the States have traditionally occupied,' we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Id.* at 1194–95 (quoting *Lohr*, 518 U.S. at 485, 116 S. Ct. 2240) (further internal quotation marks omitted).

Prior to the Court's decision in *Wyeth*, the continued validity of this so-called "presumption against pre-emption" had been in some doubt, *see, e.g., Rowe*, 448

F.3d at 74 n. 10; for that reason, perhaps, the parties here have not even mentioned the presumption in their briefing. *Wyeth*, however, clarified not only that the presumption applies against claims of implied preemption, but that it applies in this case, given "the historic presence of state law" in the field of drug labeling. 129 S. Ct. at 1194–95 & n. 3; *see also id.* at 1229 n. 14 (Alito, J., dissenting) (observing that it "remained an open question—before [*Wyeth*]—whether [the] presumption applied in conflict preemption cases"). Thus, this court must evaluate the defendants' preemption arguments in light of the assumption "that 'Congress does not cavalierly pre-empt state-law causes of action.'" *Id.* at 1195 n. 3 (quoting *Lohr*, 518 U.S. at 485, 116 S. Ct. 2240). The defendants' arguments do not withstand that level of scrutiny.

A. The plaintiffs' non-failure-to-warn claims

As an initial matter, the court notes that the defendants' arguments are directed almost entirely at the failure-to-warn aspects of the Bartletts' claims. In addition to those claims, however, the Bartletts also allege that the defendants defectively designed or manufactured Sulindac; that they breached their express and implied warranties that Sulindac was safe and fit for its intended use; and that they negligently failed to design or test Sulindac.[15F] The defendants

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[15] As discussed *supra*, the complaint also makes claims for failure to warn, fraud, and breach of implied warranty. Based on the allegations underlying those claims, the court has treated them as dependent, at least in part, on the defendants' alleged failure to warn; similarly, the court has treated the Bartletts' express warranty claim as independent of any statements in Sulindac's labeling. Ultimately, however, the proper characterization of these various claims makes no difference to the outcome of the pending motion, because the court rules that federal law does not

suggest, without fully explaining, that the Hatch–Waxman Amendments still pre-empt these claims because they depend on state law mandating "a generic drug's design to differ from that of the branded on which it is based," which is not permitted under the Hatch–Waxman Amendments.

Assuming, without deciding, that either the letter or spirit of the amendments would prevent the defendants from changing Sulindac's design, that would not conflict with the state law underlying the Bartletts' non-failure-to-warn claims. Those claims allege that the defendants violated state law by distributing a product that was defectively designed or manufactured, that was not fit for its intended use, and without using due care in designing or testing it. While one way to avoid violating state law in this way would be to redesign Sulindac to remove the alleged defect before distributing the drug (or otherwise to meet the standard of care), another way to do so would be to refrain from distributing it at all.[16]

The defendants have not offered an explanation of how state law requiring them to do so would conflict

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pre-empt even those claims that are based on allegedly inadequate warnings.

[16] And a third way to do it would be to distribute the drug only with the allegedly necessary warnings, so, if this were the only theory encompassed by the Bartletts' defective design or manufacture, warranty, and negligence claims, then the defendants' pre-emption arguments would at least be implicated. *See Good*, 501 F.3d at 36–37 (conducting pre-emption analysis by considering "how [a] particular theory—as opposed to a more generalized claim" set forth as cause of action—implicates federal law). The lack of adequate warnings, however, is not the only omission alleged in support of these claims.

with Hatch–Waxman or any other federal law.[17] At the outset, then, the defendants' motion must be denied as to the Bartletts' claims for defective design or manufacture, breach of express or implied warranties, and negligence. *See Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 427–28 (D. Vt. 2008) (ruling that negligence, strict products liability, and express and implied warranty claims were "not exclusively based on failure to add to or strengthen the warnings in FDA-approved labeling for" a generic drug and therefore not pre-empted); *Masterson v. Apotex Corp.*, No. 07–61665, 2008 WL 3262690, at *5 (S.D. Fla. Aug. 7, 2008) ("compliance with a state law duty to warn would conflict with the federal statutory scheme ... [but] preemption does not extend to manufacturing defect claims that arise separate and apart from [that] claim.").[18]

B. The plaintiffs' failure-to-warn claims

The defendants do argue, at length, that the Hatch–Waxman Amendments and their implementing regulations pre-empt the Bartletts' claims insofar as

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[17] As the Bartletts point out, the FDA regulations do require that "[a]n applicant who is the sole manufacturer of an approved drug product" give the agency at least six months' notice "prior to discontinuing manufacture," but only for drugs that are "life supporting, life sustaining, or intended for use in the prevention of a serious disease or condition" and "not originally derived from human tissue and replaced by a recombinant product." 21 C.F.R. § 314.81(b)(3)(iii)(a) (2008). There is no suggestion that Sulindac fits this narrow category.

[18] *Bolin ex rel. Bolin v. SmithKline Beecham Corp.*, No. 08–60523, 2008 WL 3286973 (S.D. Fla. Aug. 7, 2008) and *Valerio ex rel. Valerio v. SmithKline Beecham Corp.*, No. 08–60522, 2008 WL 3286976 (S.D. Fla. Aug. 7, 2008) reached the same conclusion; both were decided by the same judge, on the same day, as *Masterson*.

they arise out of the defendants' alleged failure to warn of Sulindac's potential to cause severe adverse reactions. This argument rests on the premise that, because the FDA approved Sulindac under a process that required the drug's labeling to be "the same as" that of its listed predecessor, they could not have changed the labeling—to add or strengthen a warning about such a reaction, or otherwise—without breaking, or at least standing in the way of, the federal law creating that process, the Hatch–Waxman Amendments.

1. Impossibility pre-emption

To succeed with their impossibility pre-emption argument, the defendants must show "that it would have been impossible for [them] to comply with the state-law duty to modify [Sulindac's] labeling without violating federal law," *Wyeth*, 129 S. Ct. at 1193, i.e., that " 'compliance with both federal and state [law] is a physical impossibility.'" *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153, 102 S. Ct. 3014, 73 L.Ed.2d 664 (1982) (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43, 83 S. Ct. 1210, 10 L.Ed.2d 248 (1963)). As this standard suggests, "[i]mpossibility pre-emption is a demanding defense," *Wyeth*, 129 S. Ct. at 1193. The defendants have not satisfied those demands here.

a. The Hatch–Waxman Amendments

Again, the Hatch–Waxman Amendments require that an ANDA contain "information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug," 21 U.S.C. § 355(j)(2)(A)(v), and direct the Secretary to approve an ANDA absent a finding that "information submitted in the application is insufficient" to make such a showing,

id. § 355(j)(4)(G), both with exceptions not relevant here. There is no dispute here that, absent these exceptions, Hatch–Waxman thus prevents the approval of an ANDA for a generic drug with labeling that is not "the same as" that of the listed drug; the Bartletts acknowledge as much. But the Bartletts do not seek to hold the defendants liable under state law because they failed to submit an ANDA for their generic Sulindac with labeling that was "the same as" the labeling for the pioneer version.

Rather, as noted in Part II.A, *supra*, the Bartletts allege that, after securing approval of the ANDA for generic Sulindac with the same labeling as its listed predecessor's, the defendants failed to change the label to warn adequately of the risks of Stevens Johnson–Syndrome and toxic epidermal necrolysis, despite actual or constructive knowledge of these risks. Nothing in the text of 21 U.S.C. §§ 355(j)(2)(A)(v) or (4)(G), as just quoted, prohibited the defendants from doing so.[19] The defendants point out that, likewise, "there is no provision in the FDCA *permitting* either a branded or generic manufacturer, following product approval, to change the product's labeling" (emphasis added). But that point is both irrelevant (at least as to the impossibility pre-emption analysis) and incorrect.

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[19] For this reason, the defendants are not helped by the FDA's statement in a guidance document that "[a]ll labeling changes for ANDA drug products must be consistent with section 505(j) of the Act." FDA, *Guidance for Industry: Changes to an Approved NDA or ANDA* 1 (2004), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances 24. Section 505(j) as the Act, as just discussed, requires sameness of labeling as a condition of ANDA approval; it does not restrict what happens to the label afterwards.

Impossibility pre-emption arises where federal and state law "impose directly conflicting duties," e.g., "if the federal law said, 'you must sell insurance,' while the state law said, 'you may not.'" *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 31, 116 S. Ct. 1103, 134 L.Ed.2d 237 (1996). To fit their claimed predicament into this framework, the defendants would need to show a federal law saying "You may not change your label" to conflict with the state law underlying the Bartletts' failure-to-warn claims, i.e., "You must change your label." So the defendants' assertion that the FDCA does not say *one way or the other* whether they can change their label is insufficient.

It is also incorrect, because, as discussed in part II.B.4, *supra*, the FDAMA allows, "[w]ith respect to a drug for which there is in effect an approved application under section 355 ..., a change from the manufacturing process approved pursuant to such application." 21 U.S.C. § 356a(a)(1). Both NDAs and ANDAs, of course, are approved under section 355. The FDAMA did restrict such changes: insofar as they qualify as "major manufacturing changes," they must await the Secretary's approval of a supplemental application. *Id.* § 356a(c)(1). But Congress did not classify labeling changes as "major manufacturing changes" per se, *see id.* § 356a(c)(2), and, as the CBE regulation demonstrates, neither has the FDA in exercising its authority to further define that term. *See* 21 C.F.R. § 314.70(c)(6)(iii).

Because 21 U.S.C. § 356a expressly authorizes a manufacturer's changes to an application approved under § 355 of the Act—whether under subsection (b), as in the case of an NDA, or under subsection (j), as in

the case of an ANDA—the defendants are incorrect that nothing in the Act permits a manufacturer to change its label post-approval. As another court has noted, while "Congress intended for ANDA applicants to submit identical labeling to the FDA when seeking ANDA approval, the statute is silent as to the manufacturer's obligation after the ANDA is granted." *Stacel v. Teva Pharms., USA*, 620 F. Supp. 2d 899, 907 (N.D. Ill. 2009) (citation omitted); *but see Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1064 (D. Minn. 2008) (not discussing FDAMA amendments, and holding that "under the federal statutory scheme, the labeling for generic drugs must always remain the 'same as' that of the name brand drug."), *appeal docketed*, No. 08–3850 (8th Cir. Dec. 10, 2008); *Masterson*, 2008 WL 3262690, at *4–*5 (same); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 537–38 (E.D. Pa. 2006) (similar), *aff'd on other grounds*, 521 F.3d 253 (3d Cir. 2008), *vacated*, —— U.S. ——, 129 S. Ct. 1578, 173 L.Ed.2d 672 (2009).[20] Nothing in the "statutory scheme," then, makes it impossible for a manufacturer to change the labeling of an ANDA-approved drug—or to comply with a state-law requirement that it do so.

b. FDA labeling regulations

The analysis of the defendants' impossibility argument does not end there, because "state laws can be pre-empted by federal regulations as well as by federal statutes." *Hillsborough County, Fla. v.*

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[20] In *Colacicco*, the Court of Appeals for the Third Circuit expressly did not decide "whether actions against generic drug manufacturers are preempted on the basis of their obligations under the Hatch–Waxman Amendments." 521 F.3d at 271 (footnote omitted).

Automated Med. Labs., Inc., 471 U.S. 707, 713, 105 S. Ct. 2371, 85 L.Ed.2d 714 (1985). At the outset, the court notes that some of the regulations on which the defendants rely, like the provisions of the Hatch–Waxman Amendments which those regulations implement, do not purport to restrict changes to the label of a generic drug following its approval. *See* 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7) (quoted in Part II.B.3, *supra*). Instead, those rules expressly require the generic drug's *proposed* label to be the same as that of the listed drug, and provide that an ANDA will be denied for failing to demonstrate that. *See id.*

These regulations, then, do not prevent post-approval changes to the label of an ANDA-approved drug any more than the Hatch–Waxman Act does, as a number of courts have recognized.[21] *See Demahy v. Wyeth, Inc.*, 586 F. Supp. 2d 642, 649–52 (E.D. La. 2008), *appeal docketed*, No. 08–31204 (5th Cir. Dec. 16, 2008); *Laisure–Radke v. Par Pharm., Inc.*, 2006 WL 901657, at *3–*5 (W.D. Wash. Mar. 29, 2006); *Bell v. Lollar*, 791 N.E.2d 849, 854 (Ind. Ct. App. 2003); *see also Barnhill v. Teva Pharms. USA, Inc.*, No. 06–282, 2007 WL 6947996, at *4, 2007 U.S. Dist. LEXIS 44718, at *13 (S.D. Ala. Apr. 24, 2007) (reasoning that the comments to the regulations "address labeling requirements necessary for *initial* approval, not changes to labels for approved ANDA's") (footnote

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[21] The same is true of the FDA's remarks in proposing and promulgating these regulations. *See Demahy*, 586 F. Supp. 2d at 649–52; *Barnhill*, 2007 WL 6947996, at *4, 2007 U.S. Dist. LEXIS 44718, at *13. As the quotation of one of those remarks in Part II.B.3, *supra*, illustrates, they refer to the requirement that the applicant propose the same labeling as that of the listed drug; they do not speak to what happens post-approval. *See also* 57 Fed. Reg. at 17953; 54 Fed. Reg. at 28884.

omitted); *but see Morris v. Wyeth, Inc.*, 582 F. Supp. 2d 861, 868 (W.D. Ky. 2008), *appeal docketed*, No. 09–5509 (6th Cir. Apr. 27, 2009).[22]

This is not to say that generic drug manufacturers—or any drug manufacturers, for that matter—have carte blanche to make whatever alterations they want to their labels. FDA regulations classify most "labeling changes" as "major changes," *see* 21 C.F.R. § 314.70(b)(2)(v), meaning that § 356a prohibits a manufacturer from making them without the FDA's prior approval, *see* 21 U.S.C. § 356a(c)(1). As the Supreme Court observed in *Wyeth*, "[g]enerally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application." 129 S. Ct. at 1196. But, as *Wyeth* also noted, the FDA does have a "regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval"—namely, 21 C.F.R. § 314.70(c)(iii), establishing the "CBE" supplement process. *Id.* Under this process, as discussed in Part II.B.4, *supra*, "if a manufacturer is changing a label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction,' ... it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval." *Id.* (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)).

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[22] *Wilson v. Wyeth, Inc.*, No. 07–378, 2008 WL 2677049 (W.D. Ky. June 30, 2008), *appeal docketed*, No. 09–5466 (6th Cir. Apr. 20, 2009), and *Smith v. Wyeth, Inc.*, No. 07–18, 2008 WL 4697002 (W.D. Ky. Oct. 24, 2008), *appeal docketed*, No. 09–5460 (6th Cir. Apr. 16, 2009), reached the same conclusion as *Morris*, and were decided by the same court on the same day as that case.

The Court in *Wyeth* relied on this regulation in rejecting a manufacturer's argument that state-law failure-to-warn claims were "pre-empted because it is impossible for it to comply with both the state-law duties underlying those claims and its federal labeling duties." *Id.* at 1196. The Court ruled that, once the risk of the adverse reaction experienced by the plaintiff had become "apparent," triggering a state-law duty to warn of it, "the CBE regulation permitted [the manufacturer] to provide such a warning before receiving the FDA's approval." *Id.* at 1198. While the Court acknowledged that "the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application," the Court declined to "conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements" without "clear evidence that the FDA would not have approved a change" to effect the warning at issue. *Id.* The defendants here have not presented any such evidence, i.e., that the FDA would not have approved a change to their labeling to Sulindac to strengthen the warning as allegedly required by state law.

In a supplemental memorandum (*Wyeth*, again, was decided after the parties here had already fully briefed the motion for judgment on the pleadings), the defendants nevertheless maintain that the Court's decision does not foreclose their pre-emption defense. They principally argue that, because Sulindac is a generic drug approved through an ANDA, its labeling cannot be changed through the CBE process, which applies only to NDA approved drugs; therefore, the defendants conclude, it would be impossible for them to comply with both the federal labeling scheme and the state law underlying the Bartletts' failure-to-warn

claims.[23] This court rejects with both the premise and the conclusion of that argument.

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[23] This argument assumes, of course, that the defendants could not have satisfied their state-law duty to warn by proposing to change Sulindac's label to correct the allegedly inadequate warning, obtaining the FDA's approval of that change, then making it. *Cf. Perry v. Novartis Pharm. Corp.*, 456 F. Supp. 2d 678, 685 (E.D. Pa. 2006) (ruling that, in the case of a branded drug, "state law may require a manufacturer to at least seek FDA approval for the addition of a new warning" without being pre-empted). The defendants do not expressly argue that, as ANDA holders, they are foreclosed from making a labeling change *with* the FDA's prior approval, but neither do the Bartletts allege that the defendants would have obtained such approval had they sought it. So the court need not consider this point here.

i. FDA regulations do not forbid adding or strengthening warnings to the labeling of an ANDA-approved drug through the CBE process

a. The regulations and their commentary

Just as nothing in the text of the Hatch-Waxman Amendments forbids a generic manufacturer from changing its drug's label from the listed version's post-approval, nothing in the text of the CBE regulation forbids a generic manufacturer from using the CBE process to do so. As discussed in Part II.B.4, *supra*, the CBE regulation represents the FDA's use of its authority, under the FDAMA, to designate labeling changes that add or strengthen warnings and such as "manufacturing changes that are not major manufacturing changes," 21 U.S.C. § 356a(d)(1), and that therefore can be made without prior FDA approval, *see id.* §§ 356a(d)(1)(B), (3)(B)(ii); the FDAMA, again, does not restrict this process to NDA-approved drugs. The regulation itself also imposes no such restriction: "the holder of an approved application"—not just an approved *new drug* application under subsection (b)—"may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change." 21 C.F.R. § 314.70(c)(6).

"Determining a regulation's meaning requires application of the same principles that imbue exercises in statutory construction." *Morales v. Sociedad Española de Auxilio Mutuo y Beneficencia*, 524 F.3d 54, 57 (1st Cir. 2008), *cert. denied*, 555 U.S. 1097, 129 S. Ct. 898, 173 L.Ed.2d 107 (2009). These principles include, first and foremost, "the plain meaning rule, stating that if the language of a ... regulation has a

plain and ordinary meaning, courts need look no further and should apply the regulation as it is written." *Textron, Inc. v. Comm'r*, 336 F.3d 26, 31 (1st Cir. 2003) (citing, *inter alia*, *Comm'r v. Soliman*, 506 U.S. 168, 174, 113 S. Ct. 701, 121 L.Ed.2d 634 (1993)). Because, as just discussed, nothing in the text of the CBE regulation declares its process for labeling changes off-limits to ANDA-approved drugs, it would seem "the interpretive odyssey is at an end," *Morales*, 524 F.3d at 57; like other ANDA holders, the defendants could have availed themselves of the CBE process to add or strengthen the warnings on Sulindac's labeling.[24]

To support their view that the CBE process is nevertheless unavailable to ANDA-approved drugs, the defendants rely on the FDA's remark explaining its

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[24] In their opening brief, the defendants claimed that the FDA has permitted CBE supplements seeking to add or strengthen warnings "only where the NDA holder becomes aware of newly discovered safety information" and "there is sufficient evidence of a causal association with the drug." While the publication the defendants purport to quote for this language says nothing of the sort, *see* Supplemental New-Drug Applications, 30 Fed. Reg. 993 (Jan. 30, 1965), the FDA did amend § 314.70(c)(6)(iii) in 2008—after Karen Bartlett was prescribed and took Sulindac—to limit it to "[c]hanges in the labeling to reflect newly acquired information." 73 Fed. Reg. at 49609. The Court in *Wyeth* did not "decide whether the 2008 CBE regulation is consistent with the FDCA and the previous version of the regulation," ruling that the manufacturer there "could have revised [the allegedly deficient] label even in accordance with the amended regulation." 129 S. Ct. at 1196. This court can take much the same tack here. The defendants do not argue that they could not have used the CBE supplement process to revise Sulindac's label because they lacked "newly acquired information," but only because the drug was approved on an ANDA instead of a NDA.

revision to § 314.70 following the Hatch–Waxman Amendments. That remark states, in its entirety,

> FDA received no comments on this provision, but has amended the provision to adopt references to statutory, rather than regulatory, provisions to explain what information should be provided. However, the agency wishes to remind ANDA applicants that, as noted in paragraph 4 above, the labeling for an ANDA product must, with few exceptions, correspond to that for the reference listed drug.

57 Fed. Reg. at 17955. But for the reference to "paragraph 4," this remark might provide some arguable (if atextual) support for the defendants' view: the remark, unlike others they cite, speaks of "the labeling for an ANDA product," rather than the "labeling proposed" for it, and thus might be read to require the labeling to remain the same beyond the approval process.

"Paragraph 4," though, rejects a comment that the FDA "accept ANDA's with warnings or precautions in addition to those on the reference listed drug's label," pointing out that "section 505(j)(2)(A)(v) and (j)(3)(G) of the act requires *[sic]* that the applicant's proposed labeling be the same as that of the listed reference drug" with exceptions not relevant here. *Id.* at 17953. Those provisions, again, dictate the content of the drug's labeling at the times the ANDA is submitted and approved, not afterwards. In light of the reference to "paragraph 4"—and, in turn, that paragraph's references to 21 U.S.C. § 355(j)—the FDA's comment to § 314.70 cannot be fairly read to extend the mandate that "the labeling proposed for the drug [be] the same as the labeling approved for the listed drug," 21 U.S.C.

§ 355(j)(4)(G), into the post-proposal, or post-approval, period.

Moreover, the only change the FDA made to the existing version of § 314.70 through the post Hatch–Waxman ANDA regulations was to add a paragraph requiring the applicant to "comply with the patent information requirements under [21 U.S.C. § 355(c)(2)]." *Id.* at 17983 (*later codified at* 21 C.F.R. § 314.70(e) (1993)). It is hard to believe that, in remarking upon this minor revision to the rule, the FDA was in fact expressing the view that the CBE procedures of § 314.70(c)(6)(iii)—which were not being changed, and were not mentioned anywhere in the remark—are off-limits to ANDA-approved drugs.

Indeed, as discussed in Part II.B.4, *supra*, the FDA had been letting manufacturers make labeling changes to approved drugs that added or strengthened warnings and the like, without prior agency approval, for nearly 20 years prior to Hatch–Waxman, and for more than 27 years prior to the FDA's post-Hatch-Waxman ANDA rules. *See* 30 Fed. Reg. at 993–94. And, as discussed in Part II.B.2, *supra*, the FDA had been accepting ANDAs for much of that period. If, in spite of this history, the FDA had intended to place the CBE process for labeling changes off-limits to ANDA-approved drugs in the wake of Hatch–Waxman, the agency might have been expected to do so explicitly by amending § 314.70(c)(6)(iii) to that effect—rather than by making a comment, which might or might not be read that way, while amending the rule in a different way entirely.[25]

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[25] By the same reasoning, as well as that set forth in note 21 and the accompanying text, *supra*, the FDA's remarks in revising its rules on the content and format of drug labeling say little if

What the FDA actually did was in fact markedly to the contrary: it promulgated 21 C.F.R. § 314.97, entitled "Supplements and other changes to an approved abbreviated application." 57 Fed. Reg. at 17987. The FDA enacted this provision as part of its overhaul of the ANDA rules following Hatch–Waxman, and received—and made—no comments on it. *See id.* at 17964. This rule, as mentioned in Part II.B.4, *supra*, provides: "The applicant shall comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application." The "requirements of § 314.70" referred to by § 314.97 include, of course, the CBE provision.

Had the FDA intended that, notwithstanding the clear language of § 314.97, the CBE provision was nevertheless inapplicable to drugs approved via ANDAs, one would have expected § 314.97—or the CBE provision itself—to contain language to that effect or, at least, for the FDA to have clearly explained, in

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anything about a manufacturer's power to change its labeling after the ANDA is approved. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3929 (Jan. 24, 2006) ("the labeling of a drug product *submitted for approval* under an ANDA must be the same as the labeling of the listed drug referenced in an ANDA," referring to 21 C.F.R. § 314.94(a)(8)(iv)) (emphasis added), 3963 (making the same statement in explaining that "the requirement to revise the labeling of a reference listed drug in the new format does not have any impact on the duration of exclusivity for the drug and, therefore, does not prevent a manufacturer of a generic product from using the revised labeling of the reference listed drug"). And the defendants point to nothing in the content and format rules themselves affecting a generic manufacturer's ability to add or strengthen a warning post-approval. *See* 21 C.F.R. §§ 201.56–57.

enacting those provisions, that a generic manufacturer could not use the CBE process to change its labels. But the FDA did none of these things. So the defendants are essentially asking this court to rewrite § 314.97 by tacking the words "except for § 314.70(c)(6)(iii)" onto the end.

This court, like almost all of those to have considered the availability of the CBE procedure to ANDA-approved drugs in light of § 314.97, declines to do so. *See Stacel*, 620 F. Supp. 2d at 907; *Kellogg*, 612 F. Supp. 2d at 435–36; *Demahy*, 586 F. Supp. 2d at 649–52; *Laisure-Radke*, 2006 WL 901657, at *3–*5; *accord Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) (citing § 314.97 in recognizing that manufacturers of generic drugs are "permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval"); *but see Morris v. Wyeth, Inc.*, 642 F. Supp. 2d 677, 684–85 (W.D. Ky. 2009);[26] *Mensing*, 562 F.

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[26] In *Morris*, the court denied the plaintiff's motion to reconsider its earlier ruling that his state-law failure to warn claims were pre-empted in light of, among other authorities, *Demahy*. The *Morris* court's earlier ruling had not taken § 314.97 into account. *See* 582 F. Supp. 2d 861. On reconsideration, the court discussed

> two possible interpretations of § 314.97. Either the *Demahy* court is correct that § 314.97 requires ANDA holders to utilize § 314.70, in which case whether or not an ANDA holder can unilaterally change its label is an issue currently pending before the Supreme Court, or the *Demahy* court is incorrect and § 314.97 merely states that when a brand manufacturer utilizes § 314.70, then so too must the generic manufacturer make that same change to its corresponding drug's label.

642 F. Supp. 2d at 685 (footnotes omitted).

But the court did not explain the second of these "possible interpretations" in light of either § 314.70 or § 314.97. As to the

Supp. 2d at 1064.[27] Where the language of a regulation is clear, "the courts have no warrant to rewrite [it] in the guise of 'interpretation.'" *United States v. Charles George Trucking Co.*, 823 F.2d 685, 689 (1st Cir. 1987).

That principle is particularly apt in light of what Congress had to say when it recently spoke on the labeling duties of generic drug manufacturers in the Food and Drug Amendments Act of 2007, as discussed in Part II.B.5, *supra*. Not only does that act require an ANDA holder (provided the drug is no longer marketed by its NDA holder) to submit a supplemental

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first interpretation, the court was referring to the *Wyeth* case, reasoning that "[s]hould the Court determine that brand manufacturers cannot unilaterally change their labels under § 314.70 ... then neither can generic manufacturers." *See id.* n. 3. In *Wyeth*, again, the Court held that brand-name manufacturers could unilaterally change their labels under § 314.70(c)(6)(iii)(A). 129 S. Ct. at 1198. Because the contingency essential to the first "possible interpretation" of § 314.97 did not come to pass, and because the second "possible interpretation" was left unexplained, this court declines to follow *Morris*. The same is true of two other decisions which were issued by the same come to the same court on the same day and come to the same conclusion. *Wilson v. PLIVA, Inc.*, 640 F. Supp. 2d 879 (W.D. Ky.2009); *Smith v. Wyeth, Inc.*, No. 07–18, 2009 WL 425032 (W.D. Ky. Feb. 20, 2009).

[27] In explaining away § 314.97, the court in *Mensing* relied solely on the FDA's amicus brief to the Third Circuit in *Colacicco*, which itself stated simply that § 314.97 "does not modify the requirement that the drug label for a generic drug must be the same as the label for the approved innovator drug." 562 F. Supp. 2d at 1064 (quotation formatting and emphasis omitted). Not only has that brief since been withdrawn, as noted *infra* Part III.B.1.b.i. *b*, but, in this circuit at least, courts "do not defer to [agency] views espoused only in the context of litigation," including in amicus briefs. *Rosenberg v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 170 F.3d 1, 12 (1st Cir. 1999). The court declines to follow *Mensing*.

application proposing labeling changes to reflect new safety information identified by the Secretary, or to explain why no change was warranted, 21 U.S.C. §§ 355(*o*)(4)(B), it also provides that § 355(*o*)(4) "shall not be construed to affect the responsibility of ... the holder of the approved application under [21 U.S.C. § 355(j)] to maintain its label in accordance with existing requirements, including subpart B of part 201 and section[ ] 314.70 ... of Title 21, Code of Federal Regulations (or any successor regulations)." *Id.* § 355(o)(4)(I).

As also discussed in Part II.B.5, *supra*, Title 21, part 201, subpart B of the Code of Federal Regulations requires that "[t]he labeling shall be revised to include a warning as soon as there is reasonable evidence of a serious hazard with a drug," 21 C.F.R. § 201.80(e), at least for prescription drugs not approved on an NDA, BLA, or efficacy supplement after June 30, 2001. *See id.* § 201.56(b).[28] The surest way to revise a label to include a warning "as soon as there is reasonable evidence," of course, is to make the revision through the CBE process.

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[28] Despite the clear language of 21 C.F.R. § 201.56(b)(2) that "[p]rescription drug products not described in paragraph (b)(1) of this section"—i.e., other than for which an NDA, BLA, or efficacy supplement was approved after June 30, 2001—"are subject to the labeling requirements" set forth at 21 C.F.R. § 201.80, *see* note 13, *supra*, the defendants argue that the rule "does not mean ANDAs are subject to the requirements in § 201.80; it means that any NDA drug first-approved before June 2001 is subject to the regulation." The defendants do not explain, though, how an ANDA-approved drug is anything other than a "[p]rescription drug product[ ] not described in paragraph (b)(1)." So the court rejects their interpretation.

If, as the defendants posit, the portion of § 314.70 which opens the CBE process to labeling changes adding or strengthening warnings does not apply to generic manufacturers—if, in fact, §§ 201.80(e) and 314.70(c)(6)(iii) impose no "responsibility" on ANDA holder "to maintain its label"—then the court is left to wonder, without an explanation, why Congress would have thought it necessary to clarify that 21 U.S.C. § 355(o)(4) does not affect that responsibility. The courts "assume that Congress is aware of existing law when it passes legislation." *South Dakota v. Yankton Sioux Tribe,* 522 U.S. 329, 351, 118 S. Ct. 789, 139 L.Ed.2d 773 (1998). Yet the defendants do not attempt to reconcile 21 U.S.C. § 355(o)(4) with their view that neither § 201.80(e) nor § 314.70(c)(6)(iii) applies to them.

In this void, it is reasonable to read the statute as authorizing the FDA to notify an ANDA holder of necessary labeling changes to reflect new safety information, while making clear that an ANDA holder's responsibility to make those changes on its own under 21 C.F.R. § 201.80(e), through the CBE process set forth in 21 C.F.R. § 314.70(c)(6), remains. Indeed, as *Wyeth* observed of 21 U.S.C. § 355(o)(4), "when Congress granted the FDA this authority, it reaffirmed the manufacturer's obligations and referred specifically to the CBE regulation, which both reflects the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to FDA approval." 129 S. Ct. at 1198.

The defendants also advance an argument that § 314.70(c)(6) applies only to drugs approved through the NDA process which depends not on § 314.70(c)(6) itself,

but on a different provision of the ANDA regulations, 21 C.F.R. § 314.150(b)(10). That regulation, as noted in Part II.B.3, *supra*, states:

> FDA may notify the applicant, and, if appropriate, all other persons who manufacturer or distribute identical, related, or similar drug products, and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application or the [ANDA] under [21 U.S.C. § 355(e)] and under the procedure set forth in [21 C.F.R. § 314.200], if the agency finds:
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> ...
>
> (10) That the labeling for the drug product that is the subject of the [ANDA] *is no longer consistent with* that for the listed drug referred to in the [ANDA], except for differences approved in the ANDA....

21 C.F.R. § 314.150(b) (emphasis added). The defendants argue that this rule forbade them from using the CBE process to change Sulindac's label, because doing so would have resulted in an ANDA-approved drug with labeling that was "no longer consistent with that for the listed drug," thus subjecting the ANDA to revocation. The court cannot read § 314.150 that way.

Initially, unlike the admonition repeated throughout the Hatch–Waxman Amendments, and elsewhere in the ANDA regulations, that an ANDA must show "that the labeling proposed for the new drug is *the same as* the labeling approved for the listed drug," *see, e.g.*, 21 U.S.C. § 355(j)(2)(A)(v) (emphasis added), section 314.150(b)(10) of the regulations

requires that the ANDA's labeling be "*consistent with* that of the listed drug" (emphasis added). While "same" means "being one without addition, change, or continuance," *Webster's Third New International Dictionary* 2007 (2002), the term "consistent," in contrast, means "showing no significant change, unevenness, or contradiction." *Id.* at 484.

Where two provisions of the same rule "differ in that one provision uses a term, but the other provision, where it would be equally sensible to use that term if [the agency] desired it to apply," uses a different term instead, "it is generally assumed that [the agency] acts intentionally and purposely in the disparate" wording. *United States v. Councilman*, 418 F.3d 67, 73–74 (1st Cir. 2005). Here, as one court has noted, "the discrepancy between the manifold use of the phrase 'same as' in the FDA's initial rulemaking on the *pre-approval* ANDA process is curious in comparison to the use of the phrase 'consistent with' in the regulation governing *post-approval* processes," suggesting the terms are not equivalent. *Demahy*, 586 F. Supp. 2d at 649. Labeling on an ANDA-approved drug that differs from that on the listed version only in having stronger or additional warnings is "consistent with," if not "the same as," that labeling, in that the generic's warning, contraindication, side-effect, and precaution information completely overlaps the brand name's.[29]

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[29] In proposing the regulations, the FDA noted that it would "not accept ANDA's for products with *significant* changes in labeling," on the theory that those might be necessitated by other kinds of differences from the listed drug that would "jeopardize the safe or effective use of the product." 54 Fed. Reg. at 28885 (emphasis added).

Indeed, the FDA enacted § 314.150 in response to a comment that it "should create a new provision authorizing the agency to withdraw an [ANDA] if the [ANDA] holder failed to modify its labeling to match labeling changes in the reference listed drug." 57 Fed. Reg. at 17970. The rule therefore "revised the rule accordingly" to "state[ ] that the ANDA applicant's failure to maintain drug labeling that is consistent with that of the listed drug may be grounds for withdrawing approval of the [ANDA]." *Id.* And the FDA also invoked § 314.150 in response to another comment that "FDA should create a mechanism to compel ANDA regulations to revise their labeling to conform to the listed drug product once the ANDA is approved." *Id.* at 17968.[30]

As these remarks suggest, then, "the purpose of [the] regulation was not to prevent a generic manufacturer from improving or strengthening its warnings. It was, instead, to ensure that the FDA could require a generic manufacturer to modify its labeling to match labeling changes in the reference listed drug." *Barnhill*, 2007 WL 6947996, at *4, 2007 U.S. Dist. LEXIS 44718, at *13. So, according to the FDA's own explanation for § 314.150(b)(10), it was not intended to address the opposite situation—where the ANDA holder wants to make labeling changes that have yet to be made on the listed drug.[31]

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[30] To like effect is the FDA's remark, in response to a comment on 21 C.F.R. § 314.127(a)(7), that it had "revised § 314.150 to require ANDA holders to maintain current labeling." 57 Fed. Reg. at 17968.

[31] The remarks do note that § 314.150 "permit[s] the agency to withdraw approval of the ANDA if the applicant fails to maintain labeling *in compliance with the requirements of the Act*," 57 Fed.

If anything, the FDA's remarks in promulgating its new ANDA rules after Hatch–Waxman suggest that the agency expected ANDA holders to do just that. In rejecting a comment that it allow "ANDA applicants to deviate from the labeling for the reference listed drug," the FDA noted that, "*[a]fter approval of an ANDA*, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised." 57 Fed. Reg. at 17961 (emphasis added). While at least one court has taken this statement to "underscore the notion that the ANDA drug's label must remain the same as that of the listed drug," *Mensing*, 562 F. Supp. 2d at 1062, this court sees it differently.

As the emphasized language suggests, the statement draws the familiar distinction between the near-absolute ban on labeling differences when a manufacturer proposes an ANDA and their availability "after an ANDA is approved." During that latter period, "[t]he applicant shall comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an [ANDA]," 21 C.F.R. § 314.97, or, as this remark puts it, "if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised." 57 Fed. Reg. at 17961.

Reg. at 17968 (emphasis added), but, as already discussed at length, there is nothing in "the Act" to prevent a generic drug maker from making changes to its labeling post-approval, provided that is done per the applicable procedures. *See* 21 U.S.C. § 356a.

That is precisely the process set forth by 21 C.F.R. § 314.70(c)(6)(iii).[32]

Accordingly, reading § 314.150 to allow revocation of an ANDA if its holder fails to keep up with warnings added to the listed drug's labeling—rather than if the holder uses the CBE process to add those warnings on its own—harmonizes that regulation with the rest of the FDA's ANDA rules, including §§ 314.70 and 314.97. "Otherwise, the FDA permits a generic manufacturer to strengthen or modify its labeling ..., only to suspend its approval because the new label does not conform to the label for the listed drug." *Barnhill*, 2007 WL 6947996, at *4, 2007 U.S. Dist. LEXIS 44718, at *13. This court cannot read the ANDA regulations in such a self-contradictory manner. *See, e.g., Ricci v. DeStefano*, 557 U.S. 557, 129 S. Ct. 2658, 2699, 174 L.Ed.2d 490 (2009) ("Our task in interpreting separate provisions of a single [enactment] is to give [it] the most harmonious, comprehensive meaning possible.").

***b.* The FDA's contrary amicus briefs and footnote**

As the defendants emphasize, the FDA has made statements since it promulgated the current ANDA regulations to the effect that a generic manufacturer cannot utilize the CBE process to effect a labeling change. Some of these statements were in amicus briefs the FDA filed in *Colacicco*, *supra*, first in the district court and later in the Court of Appeals for the Third Circuit. The brief to the Third Circuit, however,

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[32] Again, as discussed in Part II.B.4, *supra*, the FDA must approve all labeling changes, even those subject to the CBE process; it is just that such changes, as opposed to their "major" counterparts, are not approved until after the manufacturer has already implemented them.

was recently withdrawn, with the explanation that "the United States does not take a position on whether plaintiffs-appellants' claims in this case are preempted. The [FDA] has not yet conducted an examination of various preemption issues following the Supreme Court's decision in *Wyeth* that would be necessary to inform a position of the United States in this case." Letter from Sharon Swingle, Appellate Staff, DOJ, to Marcia M. Waldron, Clerk, Court of Appeals for the Third Circuit (Apr. 28, 2009) (on file with the Court of Appeals for the Third Circuit).[33]

The defendants also rely on the footnote in the FDA's proposed 2008 revision to § 314.70(c) asserting that "CBE changes are not available for generic drugs approved under an [ANDA] under 21 U.S.C. § 355(j). To the contrary, a generic drug manufacturer is required to conform to the approved labeling for the listed drug." 73 Fed. Reg. at 2849 n. 1. But as discussed in Part II.B.4, *supra*, the footnote does not accompany a proposal to amend § 314.70 in any way that would call for a comment on the availability of its procedures to generic drug manufacturers.[34] Nor was the language of the footnote, in any form, included in the final version of the revision. So "[t]he FDA essentially took the opportunity to make a significant statement on the preemption of generic drug labeling claims in the relative obscurity of a footnote in the

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[33] And as discussed in note 27, *supra*, an agency's statements in amicus briefs receive no particular deference from the courts of this circuit anyway. *See Rosenberg*, 170 F.3d at 12.

[34] As discussed in Part II.B.4, *supra*, the proposed (and ultimately the final) rule was "to reaffirm that a CBE supplement is appropriate to amend the labeling for an approved product only to reflect newly acquired information." 73 Fed. Reg. at 2849.

introductory statement of a document that has nothing at all to do with rules pertaining to generic drugs or to the ANDA process." *Demahy*, 586 F. Supp. 2d at 654 (emphases deleted).

Based on these concerns, the court in *Demahy* refused to accord the footnote "any significant level of deference" in deciding whether generic manufacturers can avail themselves of the CBE process for labeling changes. *Id.* This is consistent with precedent from the court of appeals. An agency's statements that "are neither adjudicatory nor the product of notice-and comment rulemaking ... are ... entitled to deference only to the extent they have the power to persuade," an approach known as "*Skidmore* deference" after *Skidmore v. Swift & Co.*, 323 U.S. 134, 65 S. Ct. 161, 89 L.Ed. 124 (1944). *Noviello v. City of Boston*, 398 F.3d 76, 90 n. 3 (1st Cir. 2005) (citing *Christensen v. Harris County*, 529 U.S. 576, 587, 120 S. Ct. 1655, 146 L.Ed.2d 621 (2000)). The FDA's footnote in its 2008 proposed regulation, which, again, was not incorporated into the final version of the rule and therefore was not subjected to the notice-and-comment procedure, fits this category. *See Stacel*, 620 F. Supp. 2d at 906; *Kellogg*, 612 F. Supp. 2d at 435.[35] Thus, "the agency must ultimately depend on the persuasive power of its argument. The simple fact that the agency *has* a position, in and of itself, is of only marginal

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[35] *Kellogg* also observed that "[t]here is no ambiguity in the regulations," since § 314.97 "plainly instructs ANDA holders to comply with § 314.70," and that no deference is therefore due the footnote under *Auer v. Robbins*, 519 U.S. 452, 117 S. Ct. 905, 137 L.Ed.2d 79 (1997). This court agrees but, in any event, the defendants do not argue that the rule is ambiguous or that *Auer* deference applies.

significance." *Mayburg v. Sec'y of HHS*, 740 F.2d 100, 106 (1st Cir. 1984) (Breyer, J.).

The FDA's footnote-bound position that "CBE changes are not available for generic drugs approved under an [ANDA] under 21 U.S.C. § 355(j)" is not persuasive, for the reasons just explained at length in Part III.B.1.b.i.a, *supra*. First, the footnote did not so much as acknowledge 21 C.F.R. § 314.97. Second, while the footnote did cite § 314.150(b)(10), that rule, as already discussed at length, provides only that the FDA may attempt to withdraw its approval of an ANDA if "the labeling for the drug product that is the subject of the [ANDA] is no longer consistent with that for the listed drug"; it says nothing at all about CBE changes, and cannot be read to prevent them in light of the other provisions of the ANDA rules. Third, while the footnote also cited certain of the agency's comments in promulgating the ANDA regulations, those comments, as also already discussed at length, do not support excluding generic manufacturers from the CBE process. Based on these deficiencies, this court joins with those others that have refused to adopt the view set forth in the FDA's footnote. *See Stacel*, 620 F. Supp. 2d at 907; *Kellogg*, 612 F. Supp. 2d at 435; *Demahy*, 586 F. Supp. 2d at 655; *but see Morris*, 642 F. Supp. 2d at 684–85 (deferring to the footnote without discussing the appropriate level of deference as a matter of administrative law); *Mensing*, 562 F. Supp. 2d at 1064 (same).[36]

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[36] The district court's opinion in *Colacicco*, *supra*, also deferred to the footnote, 432 F. Supp. 2d at 537, but, as noted above, that decision, following its affirmance by the Third Circuit, was vacated by the Supreme Court for reconsideration in light of *Wyeth*. —— U.S. ——, 129 S. Ct. 1578, 173 L.Ed.2d 672.

The defendants nevertheless argue that because, "[i]n codifying FDA's procedures, Congress clearly required generic drug labeling to be the 'same as' the pioneer drug," the FDA's footnote interpreting its regulations to that effect "is not only entitled to deference, but is 'virtually conclusive.'" (quoting *Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 380–81, 89 S. Ct. 1794, 23 L.Ed.2d 371 (1969)). This court again differs with the defendants' view.

First, while Congress did indeed "generally extend[ ] the procedures used to approve generic copies of pre–62 drugs to post–62 drugs" through the Hatch–Waxman Amendments, H.R. Rep. No. 98–857, pt. 1, at 1, 1984 U.S.C.C.A.N. at 2647, those Amendments, as is clear by now, did not in fact require the generic drug's labeling to remain the same as the pioneer's drug's post-approval; they required the labeling *proposed* in the ANDA to be the same as the pioneer drug's. *See* Part III.B.1.a, *supra*.

Second, the defendants have pointed to nothing in the rules the FDA had in place before Hatch–Waxman indicating that the agency disallowed post-approval changes to the labeling of an ANDA-approved drug. The relevant rules, both before and after their amendment in 1983, required only that an ANDA contain "[l]abeling that is in accord with *the labeling conditions described in the finding* that an [ANDA] is sufficient." 48 Fed. Reg. at 2756 *(later codified at* 21 C.F.R. § 314.2(f)(2) (1984)) (emphasis added); *see also* 35 Fed. Reg. at 6575 *(later codified* at 21 C.F.R. § 130.4(f)(2) (1971)).

As discussed in Part II.B.2, *supra*, that "finding" was the first step of the ANDA approval process prior to Hatch–Waxman, and hinged on whether the drug,

based on its approval through the DESI process, could be approved in generic form without additional clinical and pre-clinical studies—not on whether the generic drug had the same labeling as its DESI-approved version. *See* 48 Fed. Reg. at 2751 *(later codified at* 21 C.F.R. § 314.2(a) (1984)); 35 Fed. Reg. at 6575 *(later codified at* 21 C.F.R. § 130.4(f)(2) (1971)). It was not until after that finding had issued that the rules placed any restriction on labeling, and even that restriction operated only to keep the labeling proposed in the ANDA "in accord with the labeling conditions described in *the finding*," as opposed to with those of the pioneer drug.

Given that, as discussed in Part II.B.2, *supra*, the FDA retained this precise language when it amended its ANDA rules in 1983, that amendment also imposed no such restriction. To the contrary, the amendment simply limited a finding that an ANDA was suitable "to a product that was the same in active ingredient, dosage form and strength, and conditions of use as the drug product that was the subject of the finding." 48 Fed. Reg. at 2755 *(later codified at* 21 C.F.R. § 314.2(a) (1984)). This amendment did not prevent the FDA from finding, in the first step of the ANDA process, that an ANDA was suitable for a drug with labeling that differed from its DESI-approved version.

So the defendants are incorrect that, in the years prior to Hatch–Waxman, the FDA's rules disallowed ANDAs proposing labels for generic drugs that differed from those of their DESI-approved versions; the rules merely disallowed ANDAs proposing labels not "in accord with the labeling conditions described" in the agency's finding that an ANDA was suitable for that particular drug. Indeed, had FDA rules during that

time in fact done what the defendants say, the agency would not have referred to its post Hatch–Waxman rule that an ANDA show "that the proposed labeling for its drug product is the same as that of the reference listed drug" as "a *new* requirement." 54 Fed. Reg. at 28884 (emphasis added). Even if the defendants were correct, moreover, the most their assertion demonstrates is that, under the FDA's pre-Hatch-Waxman regime, an ANDA had to *propose* labeling that was the same as the pioneer drug's. As in the case of the Hatch–Waxman Amendments themselves and the FDA's implementing regulations, it simply does not follow that the labeling had to *remain* the same after the ANDA had been approved.

c. The presumption against pre-emption

As just discussed in exhaustive detail, that point is clear from the text of the statute and the regulations. But even if the defendants, through the footnote and certain other portions of the FDA comments on its ANDA rules, were able to cast some doubt on whether generic manufacturers can use the CBE process to make labeling changes, that doubt could not be resolved in the defendants' favor. As *Wyeth* makes clear, a court must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." 129 S. Ct. at 1194–95. For the reasons just discussed at length—in particular, the absence of any ban on labeling changes to an ANDA-approved drug in either the Hatch–Waxman Amendments or their implementing rules—that presumption cannot be overcome here.

This is not to say that Congress could not have passed legislation to give the FDA, rather than state

authorities or juries, the final say-so on the content of generic drug labeling, much as Congress has done in the case of medical devices. *See id.* at 1200 (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S. Ct. 999, 169 L.Ed.2d 892 (2008)). It is just that, without evidence of such a "clear and manifest purpose" to pre-empt state law, this court must presume that federal law is not to be read to that effect. The defendants cannot overcome that presumption here, even if any and all arguable inconsistencies in the FDA's commentary are resolved in the defendants' favor. *See Stacel*, 620 F. Supp. 2d at 906–07; *Kellogg*, 612 F. Supp. 2d at 436; *but see Mensing*, 562 F. Supp. 2d at 1061 (declining to apply the presumption, pre-*Wyeth*).

ii. Even read as the defendants suggest, the regulations do not make compliance with state law impossible

Finally, even if the defendants were correct that they could not use the CBE process to make unilateral changes adding or strengthening warnings to their generic drug, it does not follow that compliance with state law requiring such warnings is impossible. In *Wyeth*, the Court rejected the drug manufacturer's argument that "if it had unilaterally added ... a warning, it would have violated federal law governing unauthorized distribution and misbranding ... on the assumption that this labeling change would have rendered [its drug] a new drug lacking an effective application." 129 S. Ct. at 1197.

The Court reasoned, first, "strengthening the warning would not have rendered [the manufacturer's drug] a new drug" (citing 21 U.S.C. § 321(p)(1) and 21 C.F.R. § 310.3(h)) and, second,

> Nor would this warning have rendered [the drug] misbranded. *The FDCA does not provide that a drug is misbranded simply because the manufacturer has altered an FDA-approved label;* instead, the misbranding provision focuses on the substance of the label and, among other things, proscribes labels that fail to include 'adequate warnings.' 21 U.S.C. § 352(f). Moreover, because the statute contemplates that federal juries will resolve most misbranding claims, the FDA's belief that a drug is misbranded is not conclusive.

Id. (emphasis added).

The same reasoning applies with equal force here. Even if § 314.150(b)(10) forbids a generic manufacturer from using the CBE procedure to strengthen its label, the FDA would have to enforce that prohibition through proceedings to withdraw its approval of the ANDA under 21 U.S.C. § 355(e). Like the misbranding trials discussed by the Court in *Wyeth*, the outcome of such a proceeding ultimately turns not on whether the label is in fact "consistent with" that of the listed version, but on whether "such drug is unsafe under the conditions of use upon the basis of which the application was approved" or "there is lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. §§ 355(e)(1), (3). So, even if the defendants were correct that § 314.150(b)(10) required them to keep the same label on their generic Sulindac as that on the listed version, it is hardly a foregone conclusion that breaking the rule by strengthening a particular

warning without prior FDA approval would result in revocation of their ANDA for the drug.[37]

The upshot is that, at best, the defendants can show "a hypothetical or potential conflict ... insufficient to warrant pre-emption." *Rice v. Norman Williams Co.*, 458 U.S. 654, 659, 102 S. Ct. 3294, 73 L.Ed.2d 1042 (1982). The defendants have offered no reason to believe that the FDA would begin revocation proceedings against them for strengthening the warning, and no reason to believe that those proceedings would actually lead to revocation under § 355(e). They have not met the demands of impossibility pre-emption. *See Wyeth*, 129 S. Ct. at 1197–98; *Kellogg*, 612 F. Supp. 2d at 430.

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[37] There is also the *Wyeth* Court's point that "the very idea that the FDA would bring an enforcement action for strengthening a warning pursuant to the CBE is difficult to accept—neither [the defendants] nor the United States has identified a case in which the FDA has done so." 129 S. Ct. at 1197. Thus, while non-enforcement of a prohibition does not necessarily have any legal consequence, the Court in *Wyeth* reasoned that the historical lack of a misbranding prosecution arising out of a strengthened warning at least tended to undermine the manufacturer's impossibility argument.

2. Frustration-of-purpose pre-emption

The defendants also claim that the state law underlying the plaintiffs' failure-to-warn claims "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in the Hatch–Waxman Amendments. *Good*, 501 F.3d at 47. Specifically, the defendants argue that state-law requirements that a manufacturer alter the warning on an ANDA-approved drug post-approval will necessarily entail duplicative clinical trials "necessary to generate the data that might put generic companies on notice that label changes are warranted." This testing, the argument goes, will drive up the price of generic drugs in contravention of one of Hatch–Waxman's goal "to make available more low cost generic drugs by establishing a generic drug approval procedure for drugs approved after 1962." H.R. Rep. No. 98–857, pt. 1, at 14, 1984 U.S.S.C.A.N. at 2647. There are a number of serious problems with this argument.

At the outset, the defendants do not identify anything in the statutory or regulatory provisions on manufacturing changes, 21 U.S.C. § 356a and 21 C.F.R. § 314.70, requiring that manufacturers justify heightened warnings with the results of their own clinical trials. Those provisions, in fact, contain no such requirement. *See* 21 U.S.C. §§ 356a(d)(3)(A), 21 C.F.R. § 314.70(c)(3). And another FDA rule, as discussed in Part II.B.5, *supra*, requires that "labeling shall be revised to include a warning as soon as there is reasonable evidence of a serious hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.80(e). If anything, then, the regulatory scheme actually contemplates that manufacturers add

warnings to their labels without conducting clinical trials; it in no way makes those trials a prerequisite to such additions. So the premise of the defendants' argument is defective.

Furthermore, as also discussed in Part II.B.5, *supra*, FDA rules enacted to carry out the Hatch–Waxman Amendments specifically require ANDA holders to adhere to the agency's rules on "the reporting and recordkeeping of adverse drug experiences," 21 C.F.R. § 314.98(a), which include, among other things, a mandate for "written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA," *id.* § 314.80(b). These requirements naturally impose costs on generic drug makers, driving up the costs of their products. Yet the FDA has chosen to subject generic manufacturers to its monitoring and reporting requirements anyway. This strongly suggests that the similar requirements of state products liability law do not stand as an obstacle to Hatch–Waxman's cost-cutting objectives.[38]

As discussed in Parts II.B.1–2, *supra*, Congress pursued those objectives through the Hatch–Waxman Amendments by relieving generic drug manufacturers of the burdens of safety and effectiveness testing as a condition of approval. The defendants have pointed to nothing in the Amendments, their legislative history,

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[38] A different kind of state-law claim could theoretically have this effect: for example, a claim that a manufacturer of an ANDA-approved drug was negligent in failing to conduct clinical trials prior to its approval. But that is not this case, where the Bartletts allege that "reports of serious adverse events associated with Sulindac ... in the medical literature"—rather than independent testing—sufficed to put the defendants on notice that a stronger warning was appropriate.

the FDA's rules enforcing them, or the agency's comments in making those rules to indicate that Congress also sought to relieve generic drug manufacturers of any of the burdens of state products liability law. There is little doubt that doing so *would* likewise reduce the cost of generic drugs, but it does not follow that Congress intended that state laws having the opposite effect should perish on the strength of Hatch–Waxman.[39]

As the court of appeals has instructed, "it is not the fact of [federal] action on a particular subject alone—but the reasons for the action—that control its preemptive effect." *Good*, 501 F.3d at 55. Lacking any evidence that Congress passed the Hatch–Waxman Amendments intending to displace state-law labeling requirements on generic drugs, the defendants have provided no basis for finding those requirements pre-

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[39] The defendants' reliance on Justice Breyer's concurring opinion in *Wyeth* is therefore misplaced. He noted that "some have argued that state tort law can sometimes raise prices to the point where those who are sick are unable to obtain the drugs they need" and that, in such a case, the FDA may determine that state tort law serves as "a hindrance to achieving the safe drug-related medical care that Congress sought." 129 S. Ct. at 1204. Thus, Justice Breyer observed, the FDA "may seek to embody those determinations in lawful specific regulations describing, for example, when labeling requirements serve as a ceiling as well as a floor. And it is possible that such determinations would have pre-emptive effect." *Id.* The defendants, however, point to nothing to suggest that either Congress or the FDA determined that *state tort law*—as opposed to federal drug-approval requirements—was acting as a hindrance to "safe drug-related medical care" by driving up generic drug prices. Thus, whatever the proper reading of FDA rules as they govern labeling changes to ANDA-approved drugs, those rules do not "embody" any determination to displace state tort law. So Justice Breyer's observations are inapposite here.

empted by the Amendments. Nor have the defendants overcome the assumption, endorsed by the *Wyeth* Court, that "[i]f Congress thought that state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision" directed at those suits as part of Hatch–Waxman. 129 S. Ct. at 1199. Here, as there, the fact that Congress did no such thing strongly indicates that Congress meant to do no such thing. Again, "the purpose of Congress is the ultimate touchstone in every preemption case." *Id.* at 1194 (internal quotation marks omitted).

In that vein, the defendants' frustration-of-purpose argument (and their impossibility argument, for that matter) raises another serious difficulty: leaving those injured by drugs unaccompanied by warnings deemed adequate by state law without any remedy at all without any indication that Congress desired, or even contemplated the possibility, of such a result.[40] While

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[40] The vast majority of courts have rejected the notion that the manufacturer of the brand-name drug may be liable for defects in its generic equivalent on a theory of "innovator liability." *See, e.g.*, *Foster*, 29 F.3d at 171; *Goldych v. Eli Lilly & Co.*, No. 04–1477, 2006 WL 2038436, at *6 (N.D.N.Y. July 19, 2006); *Colacicco*, 432 F. Supp. 2d at 543; *Block v. Wyeth, Inc.*, No. 02–1077, 2003 WL 203067, at *2–*3 (N.D. Tex. Jan. 28, 2003); *Sharp v. Leichus*, No. 2004–0643, 2006 WL 515532, at *3–*5 (Fla. Cir. Ct. Feb. 17, 2006); *Kelly v. Wyeth*, No. 2003–03314, 2005 WL 4056740, at *4 (Mass. Super. Ct. May 6, 2005); *but see Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299, 318 (2008). While this court need not decide whether New Hampshire would recognize such a theory, its widespread rejection supports the view that, if failure-to-warn claims against generic drug makers are indeed pre-empted, those injured as a result of deficient warnings on those products have no recourse. The defendants did not dispute this point at oral argument, suggesting instead that consumers who opt for generic drugs over name-brand equivalents may have effectively lost their right to recompense for injuries suffered from inadequate

Congress could have thought this a necessary consequence of lowering the costs of prescription drugs, "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449, 125 S. Ct. 1788, 161 L.Ed.2d 687 (2005).

But, as just discussed at length, Congress did not do so. Without such a clear expression of intent, this court refuses to take that step on its own. This puts this court in line with others to consider the issue. *See Stacel*, 620 F. Supp. 2d at 907; *Kellogg*, 612 F. Supp. 2d at 430–31; *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262, 1265–66 (W.D. Okla. 2009); *Laisure–Radke*, 2006 WL 901657, at *6; *accord Foster*, 29 F.3d at 170 ("The statutory scheme governing premarketing approval for drugs simply does not evidence Congressional intent to insulate generic drug manufacturers from liability ... or ... to alter state products liability law"). The defendants have not shown that the state-law requirements underlying the Bartletts' failure-to-warn claims present an obstacle to the accomplishment and execution of the full purposes and objectives of Congress in the Hatch–Waxman Amendments or their implementing regulations.

III. *Conclusion*

For the foregoing reasons, the defendants' motion for judgment on the pleadings is DENIED.

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warnings in the bargain. That suggestion is not only distasteful but also contrary to fundamental principles of tort law.

United States Code Annotated
Title 21. Food and Drugs
Chapter 9. Federal Food, Drug, and Cosmetics
Subchapter II. Definitions

§ 321. Definitions; generally

Effective: June 22, 2009

For the purposes of this chapter--

* * *

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

* * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

* * *

United States Code Annotated
Title 21. Food and Drugs
Chapter 9. Federal Food, Drug, and Cosmetic Act
Subchapter V. Drugs and Devices
Part A. Drugs and Devices

§ 355. New drugs

Effective: March 23, 2010

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

* * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain--

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that

the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to

the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

* * *

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

* * *

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds--

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

* * *

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds--

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show--

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title, or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of

administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this

subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

* * *

OPPOSITION BRIEF

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No. 12-142

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

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October 31, 2012

QUESTION PRESENTED

Whether this Court should grant certiorari to review the First Circuit's conclusion that federal law does not preempt respondent's strict products liability claim seeking compensation for severe injuries resulting from use of a generic pain medication manufactured by petitioner, where the First Circuit's decision does not conflict with any decision of this Court or of any other court of appeals.

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The petition erroneously attempts to depict the court of appeals' decision as having blatantly departed from this Court's holding in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). In *PLIVA*, this Court held that federal law preempted state tort suits premised on the alleged failure of manufacturers of a generic drug to warn patients about one of that drug's side effects. The Court concluded that federal law prohibited the manufacturers from providing warnings different from those approved for the corresponding brand-name medication. Because it therefore would have been *impossible* for the manufacturers to comply with a state-law duty to provide an additional warning, the state-law claims were preempted.

In this case, respondent Karen Bartlett suffered grievous injuries after taking sulindac, a generic pain medication manufactured by petitioner. The district court dismissed Ms. Bartlett's failure-to-warn claim before trial, and her suit against petitioner was tried to a jury on one theory: that sulindac was unreasonably dangerous because its risks outweighed its benefits. The jury found liability, and the First Circuit affirmed. In response to petitioner's argument that Ms. Bartlett's state-law claim is preempted under *PLIVA*, the court of appeals explained that, unlike in *PLIVA*, compliance with both federal and state law is not *impossible* here because New Hampshire law does not require petitioner to take any action that federal law prohibits.

Petitioner fails to show that the First Circuit's decision created a circuit conflict, and its arguments that the court of appeals erred or departed from *PLIVA* lack merit. Petitioner's disagreement with the First Circuit principally concerns the proper interpretation of New Hampshire law – a dispute that in all events does not warrant this Court's review.

STATEMENT

1. This case "arises out of severe and permanent injuries sustained by plaintiff Karen Bartlett after taking sulindac, a generic non-steroidal anti-inflammatory drug ('NSAID') manufactured by" petitioner. App. 3a. Sulindac "is known to cause" a condition called "Stevens-Johnson Syndrome and its more generic cousin toxic epidermal necrolysis ('SJS/TEN')." *Id.* SJS/TEN is a severe allergic reaction characterized by extensive loss of skin. Sulindac "is a recognized cause of SJS/TEN – potentially a leader among NSAIDs in that respect – and the drug carries other risks as well." App. 23a.

In December 2004, Ms. Bartlett visited her doctor complaining of shoulder pain. Ms. Bartlett's physician prescribed sulindac "under the brand-name Clinoril made by the original provider, and her pharmacist dispensed generic sulindac" manufactured by petitioner. App. 3a; *see* App. 32a.

"The consequences were," in the First Circuit's words, "disastrous." App. 3a. In early 2005, Ms. Bartlett developed SJS/TEN. *Id.* "TEN is diagnosed when 30 percent or more of the outer skin layer on a patient's total body surface area has deteriorated, been burned off or turned into an open wound." *Id.* In Ms. Bartlett's case, "the percentage rose to 60-65 percent of her body." *Id.*

The First Circuit characterized Ms. Bartlett's injuries as "truly horrific," and her burn surgeon "described the experience as 'hell on earth.'" App. 22a-23a. Ms. Bartlett "spent months in a medically-induced coma," "spent a year being tube fed," and "endured two major septic shock episodes." *Id.* "She suffered through 12 eye surgeries and has many more ahead of her." App. 23a. As the district court

stated, "[n]o one who witnessed the trial in this case could deny the horror of Bartlett's injuries." App. 101a.

Ms. Bartlett's "permanent damage is severe." App. 23a. She "cannot eat normally due to esophageal burns, cannot have sexual relations due to vaginal injuries, and cannot engage in aerobic activities due to lung injuries." *Id.* Ms. Bartlett "is almost blind now and faces some likelihood of complete and permanent blindness." *Id.* She "cannot read or drive to work," and she "is seriously disfigured in face and body." *Id.* That is only "a brief summary of the suffering detailed for the jury." *Id.*

2.a. Ms. Bartlett filed suit against petitioner in New Hampshire state court, asserting products-liability claims under New Hampshire law. *See* App. 3a, 32a. After petitioner removed the action to federal court, the district court granted summary judgment for petitioner on Ms. Bartlett's claim that petitioner failed adequately to warn of sulindac's risks. *See* App. 3a-4a, 32a-34a. The court concluded that, in light of the testimony of Ms. Bartlett's doctor that he had not read the drug's labeling, Ms. Bartlett could not prove causation for a failure-to-warn claim. *See id.*

Ms. Bartlett's remaining claim was "that sulindac's risk[s] outweighed its benefits, making it a defective product unreasonably dangerous to consumers." App. 35a; *see* App. 4a. New Hampshire has adopted the theory of strict products liability set forth in Section 402A of the Restatement (Second) of Torts (1965).[1] Section 402A holds the seller of "any prod-

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[1] *See Kelleher v. Marvin Lumber & Cedar Co.*, 891 A.2d 477, 492 (N.H. 2005).

uct in a defective condition unreasonably dangerous to the user or consumer" strictly liable for any injuries caused by the product, irrespective of whether "the seller has exercised all possible care in the preparation and sale of his product." Restatement § 402A(1)-(2); *see id.* cmt. a. Strict liability is justified because "the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it," and "the burden of accidental injuries caused by products intended for consumption [should] be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained." *Id.* cmt. c.

Comment k to § 402A creates an exemption from strict liability for "[u]navoidably unsafe products," which are defined as those that, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." *Id.* cmt. k. Such products are not considered "defective" or "*unreasonably* dangerous," and therefore are exempt from strict liability, "notwithstanding the unavoidable high degree of risk which they involve." *Id.* To qualify for comment k's exemption from strict liability, the product in question must be not only "unavoidably unsafe" but also "properly prepared, and accompanied by proper directions and warning." *Id.*

During pre-trial proceedings, petitioner asserted a "comment k" defense. But, "on the eve of trial, without explanation," petitioner abandoned that defense. App. 36a; *see* App. 7a, 30a. With petitioner's "'comment k' defense out of the case, the adequacy of sulindac's warning . . . was no longer an issue for trial." App. 36a.

b. In August and September 2009, the district court held a 14-day trial. Ms. Bartlett presented, among other evidence, expert testimony from a pharmacologist/toxicologist showing "that sulindac had a worse record of causing SJS/TEN than other available drugs, and a safety profile similar to other drugs deemed dangerous enough to have been withdrawn from the market." App. 4a-5a; *see also* App. 39a-58a (discussing evidence on risks and benefits).

Petitioner had designated its own expert on that topic, as well as other witnesses. *See* App. 5a. But petitioner "chose not to call any of its own witnesses at trial, foregoing the opportunity to rebut Bartlett's evidence and put sulindac in a better light." App. 30a-31a; *see also* App. 49a (petitioner evidently "chose not to present its own experts because it feared that they would actually strengthen, not weaken, Bartlett's case").

The jury rendered a verdict for Ms. Bartlett and awarded $21.06 million in compensatory damages. *See* App. 5a, 39a. The district court denied petitioner's post-trial motions for judgment as a matter of law and for a new trial. *See* App. 29a-103a.

3. The First Circuit affirmed. Relevant here, the court of appeals rejected petitioner's contention that federal law preempts Ms. Bartlett's claim. The court recognized that New Hampshire's common law "imposes liability for selling any product in a defective condition unreasonably dangerous to the user or consumer when the product causes injury to the user or consumer." App. 6a (internal quotations omitted). To prevail on that theory, an injured consumer need not show that there existed a safer alternative design that the manufacturer could have adopted. *See* App. 6a-7a. In addition, as the First Circuit understood

the record, sulindac cannot, in any event, be "made in a different and safer form" because it "is a one-molecule drug; and the variations in sulindac as sold consist of inactive ingredients that ordinarily do not have significant pharmacological effects." App. 6a.

In light of New Hampshire law and the facts of this case, the First Circuit concluded that nothing in federal law renders compliance with state law impossible. The court observed that, consistent with federal law, petitioner "certainly can choose not to make the drug at all." App. 10a.

The First Circuit explained that this Court's decision in *PLIVA* did not require a different conclusion. There, this Court held that federal law "preempts failure-to-warn claims against generic drug manufacturers" because "[g]eneric drug manufacturers, unlike brand-name manufacturers, cannot unilaterally change their labels" under federal law, and thus cannot comply with a state-law duty to provide a stronger warning. App. 9a-10a. Here, however, the manufacturer can comply with state law without running afoul of federal law: although "the generic maker has no choice as to label," "the decision to make the drug and market it in New Hampshire is wholly its own." App. 10a-11a.

The First Circuit also rejected the notion that New Hampshire law as applied in this case constitutes an unacceptable obstacle to the accomplishment of Congress's purposes and objectives. It noted that, in *Wyeth v. Levine*, 555 U.S. 555 (2009), this Court rejected purposes-and-objectives preemption in the drug context, "saying that 'Congress did not intend [Food and Drug Administration ("FDA")] oversight to be the exclusive means of ensuring drug safety and effectiveness' and that state law serves as a 'comple-

mentary form of drug regulation.'" App. 9a (quoting *Levine*, 555 U.S. at 575, 578) (citations omitted). Against that backdrop, the First Circuit perceived nothing in federal law that would preclude "states [from] tell[ing]" petitioner that "it ought not be" selling sulindac "if risk-benefit analysis [weighs] against the drug." App. 10a.

REASONS FOR DENYING THE PETITION

I. THE PETITION FAILS TO JUSTIFY THIS COURT'S INTERVENTION

A. There Is No Circuit Conflict

There is no circuit conflict that might warrant this Court's review. Aside from failure-to-warn claims against generic drug manufacturers, which this Court addressed in *PLIVA*, the courts of appeals have generally concluded, consistent with the decision below, that federal drug regulation does *not* preempt state products-liability actions.[2] The court of appeals' decision in this case is the first – and only – post-*PLIVA* circuit court decision to address whether federal law preempts tort claims against generic drug manufacturers involving theories other than failure to warn. Further review of the issue is unwarranted at this time.

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[2] *See, e.g., Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 537-38 (6th Cir. 1993) ("We reject the argument that FDA approval preempts state product liability claims based on design defect.") (citing *Hurley v. Lederle Lab. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176-77 (5th Cir. 1988)); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 343 n.16 (2008) (Ginsburg, J., dissenting) (collecting cases); *see also Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 390-91 (7th Cir. 2010) ("Until the early 2000s, prescription drug companies infrequently invoked the preemption defense, and when they did, it rarely succeeded.").

Petitioner incorrectly asserts that, after *PLIVA*, other courts of appeals have "considered . . . state law *design-defect* claims" – which this Court did not consider in *PLIVA* – and "found them to be preempted." Pet. 19 (emphasis added). In fact, the court of appeals decisions that petitioner cites (*see id.*) addressed only *failure-to-warn* claims (the same type of claim addressed by this Court in *PLIVA*).

In *Gaeta v. Perrigo Pharmaceuticals Co.*, the district court held that the "Plaintiffs' causes of action are preempted to the extent that they allow for liability *based on a lack of adequate warning* on the company's [over-the-counter] generic drug labeling." 562 F. Supp. 2d 1091, 1098 (N.D. Cal. 2008) (emphasis added).[3] After the plaintiffs stipulated that the district court's order disposed of all of their claims, the district court entered a final judgment, and the plaintiffs appealed.[4] The Ninth Circuit reversed, addressing only failure to warn and holding that "federal law does not preempt state law failure-to-warn claims against generic manufacturers, provided there is no 'clear evidence' that the FDA would not have approved the proposed stronger warning." 630 F.3d 1225, 1227 (9th Cir. 2011); *see also id.* at 1230 (describing the "focal issue in th[e] appeal" as whether *Levine* applies to claims against generic manufacturers), 1239 (summarizing holding).

This Court subsequently granted the manufacturers' certiorari petition, vacated the Ninth Circuit's

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[3] *See also* 672 F. Supp. 2d 1017 (N.D. Cal. 2009) (denying post-judgment motion for reconsideration in light of *Wyeth v. Levine*).

[4] *See* Order re: Pls.' Objection, No. C 05-04115 JW (N.D. Cal. July 25, 2008) (ECF No. 251); Am. Judgment, No. C 05-04115 JW (N.D. Cal. Dec. 15, 2008) (ECF No. 330).

judgment, and remanded for further consideration in light of *PLIVA*. *See L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497 (2011). On remand, the Ninth Circuit affirmed "the district court's grant of summary judgment in favor of [the defendants]," 469 F. App'x 556, 557 (9th Cir. 2012) – a decision that, as noted, was limited to preemption of claims based on a failure to warn, *see* 562 F. Supp. 2d at 1098.

Similarly, in *Smith v. Wyeth, Inc.*, "the assertion that Defendants failed to adequately warn [the plaintiff] of the long-term negative effects of" the drug in question was "[c]entral to all of" the plaintiff's claims. No. 5:07-CV-18-R, 2008 WL 4697002, at *1 (W.D. Ky. Oct. 24, 2008).[5] In affirming the dismissal

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[5] *See also* 2008 WL 4697002, at *2-*6. The district court issued essentially identical opinions in the other two cases that were consolidated before the Sixth Circuit in *Smith*. *See* Mem. Op., *Wilson v. Wyeth, Inc.*, No. 3:07-CV-378-R (W.D. Ky. Oct. 24, 2008) (ECF No. 83); Mem. Op., *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R (W.D. Ky. Oct. 24, 2008) (ECF No. 93).

In a subsequent order in *Smith*, the district court specified that the plaintiff in that case "did not allege a design defect claim." No. 5:07-CV-18-R, 2009 WL 425032, at *1 n.2 (W.D. Ky. Feb. 20, 2009). Although the court suggested that the plaintiffs in *Wilson* and *Morris* had pleaded such claims, it "decline[d] to consider th[e] issue . . . until it is properly briefed by both parties in a separate motion before the Court." Mem. Op. at 2 n.2, *Wilson v. PLIVA, Inc.*, No. 3:07-CV-378-R (W.D. Ky. Feb. 20, 2009) (ECF No. 98); Mem. Op. at 3 n.2, *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R (W.D. Ky. Feb. 20, 2009) (ECF No. 110). Neither plaintiff elected to pursue a non-warning claim. *See* Order, *Wilson v. Wyeth, Inc.*, No. 3:07-CV-378-R (W.D. Ky. Feb. 20, 2009) (ECF No. 100) (noting parties' agreement that the court's disposition of the case was final and suitable for appeal); Order, *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R (W.D. Ky. Feb. 23, 2009) (ECF No. 112) (same); Order, *Wilson v. PLIVA, Inc.*, No. 3:07-CV-378-R (W.D. Ky. Mar. 20, 2009) (ECF No. 102)

of those claims as preempted, the Sixth Circuit focused exclusively on failure-to-warn liability, following *PLIVA* in affirming the district court's conclusion that the "state-law failure-to-warn claims against the generic defendants" were preempted. 657 F.3d 420, 423 (6th Cir. 2011).

Petitioner's reliance on the Fifth and Eighth Circuits' decisions on remand from this Court's decision in *PLIVA* is equally misplaced. As those cases came to this Court, neither involved non-warning claims. The district court in *PLIVA* noted that "at the core of all of Plaintiff's claims is the basic assertion that [the generic manufacturers] failed to adequately warn about" a particular risk. *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1058 (D. Minn. 2008).[6] On appeal, the plaintiff did "not challenge[] the district court's characterization that 'at the core' [her claims] all assert[ed] failure to warn." *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009) (quoting 562 F. Supp. 2d at 1058).[7] Accordingly, the Eighth Circuit addressed only "the generic defendants' argument that federal law preempts state failure to warn claims against them." *Id.*

Likewise, in the Fifth Circuit case that this Court consolidated with *PLIVA*, the district court had denied the generic manufacturer's motion to dismiss the plaintiff's failure-to-warn claim, *see Demahy v. Wyeth Inc.*, 586 F. Supp. 2d 642, 643-62 (E.D. La.

(final judgment); Order, *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R (W.D. Ky. Mar. 20, 2009) (ECF No. 117) (same).

[6] *See* 562 F. Supp. 2d at 1061 n.6 ("[A]ll of Plaintiff's claims are essentially 'failure to warn' claims and are encompassed by the Court's preemption analysis.").

[7] *See also* 588 F.3d at 604 (describing suit as a "failure to warn and misrepresentation case").

2008), and had certified that ruling for interlocutory appeal as a "controlling question of law." Order, *Demahy v. Wyeth Inc.*, No. 08-CV-3616 (E.D. La. Nov. 14, 2008) (ECF No. 40). The Fifth Circuit thus explained that the case "present[ed] one issue on appeal: whether the federal regulatory regime governing pharmaceuticals preempts state-law failure-to-warn claims against manufacturers of generic drugs." *Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010); *see also* Br. of Appellee Julie Demahy at 2, No. 08-31204 (5th Cir. filed Mar. 30, 2009) (identifying only failure-to-warn theory in discussing claims).

After this Court reversed the Fifth and Eighth Circuits' judgments in *PLIVA*, the Eighth Circuit on remand vacated the portions of its prior opinion that addressed preemption and entered a judgment affirming the district court's decision, which (as noted) was limited to preemption of claims based on a failure to warn. *See Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011); Judgment, *Mensing v. Wyeth, Inc.*, No. 08-3850 (8th Cir. Sept. 29, 2011). The Fifth Circuit similarly vacated the district court's order denying the defendant's motion to dismiss and remanded for entry of judgment in favor of the defendant. *See Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011) (per curiam).

In short, petitioner has identified no other circuit court decision addressing whether federal law preempts design-defect or other non-warning claims involving generic drugs. Its assertion (at i, 6, 18, 34) of a "circuit split" is therefore erroneous.

B. The Petition Provides No Basis For Granting Review In The Absence Of A Circuit Conflict

Petitioner fails to show that this case justifies an exception from this Court's general practice of "permitting several courts of appeals to explore" an issue and "waiting for a conflict to develop" before granting review. *United States v. Mendoza*, 464 U.S. 154, 160 (1984).

1. The petition does not present a question of recurring national importance

Strict-liability claims asserting that the design of a prescription drug is defective – that is, cases premised on a defect in the design of the drug itself, as opposed to a failure to warn about a hazard posed by the drug as designed – are rare and exceedingly difficult to prove.[8]

Courts in several states have declined altogether to recognize strict-liability claims based on the design of a prescription drug.[9] Those states' courts have taken the view that prescription drugs are, by definition, "unavoidably unsafe" within the meaning of the Restatement's comment k. *See supra* pp. 3-4 (discussing

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[8] *See generally* App. 5a ("courts 'traditionally have refused to review the reasonableness of the designs of prescription drugs'") (quoting Restatement (Third) of Torts: Products Liability § 6 cmt. f (1998) (Reporter's Note)).

[9] *See, e.g.*, *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003); *Hahn v. Richter*, 673 A.2d 888, 889-91 (Pa. 1996); *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993); *Brown v. Superior Court*, 751 P.2d 470, 482-83 (Cal. 1988); *Edwards v. Basel Pharm.*, 933 P.2d 298, 300 (Okla. 1997); *Wimbush v. Wyeth*, 619 F.3d 632, 637 (6th Cir. 2010) (Ohio law); *Tatum v. Schering Corp.*, 795 F.2d 925, 926 (11th Cir. 1986) (Alabama law); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 658 (D. Md. 2011) (Maryland law), *cited in* Pet. 19.

Restatement and comment k). Thus, in those jurisdictions, alleged defects in a drug's design do not support a claim for strict products liability. Rather, to establish liability, an injured patient must prove either that the manufacturer failed to warn of a foreseeable risk or that the drug was not properly manufactured.

Other states apply comment k on a case-by-case basis.[10] In those jurisdictions, if a manufacturer makes a case-specific showing that the drug in question is "unavoidably unsafe," it will qualify for comment k's exemption from strict products liability. Although design-defect claims are possible in those jurisdictions, a plaintiff seeking to overcome a manufacturer's reliance on comment k still must show that the hazard that caused her injury was "avoidable" – a very high hurdle.[11]

Many states also require patients to prove as an element of their case the existence of a safer alternative design for the drug that the manufacturer could have adopted. *See* La. Rev. Stat. Ann. § 9:2800.56; *Eckhardt v. Qualitest Pharm. Inc.*, 858 F. Supp. 2d

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[10] *See generally* 5 Louis R. Frumer & Melvin I. Friedman, *Products Liability* § 50.03A[3], at 50-59 to 50-61 (2012) (collecting cases and discussing "the wide adoption of comment k").

[11] Under the approach of the most recent Restatement, a prescription drug is unreasonably dangerous only "if the foreseeable risks of harm posed by the drug . . . are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . *for any class of patients*." Restatement (Third) of Torts: Products Liability § 6(c) (emphasis added). According to the accompanying commentary, "[g]iven this very demanding objective standard, liability is likely to be imposed only under *unusual circumstances*." *Id.* § 6 cmt. f (emphasis added).

792, 801 (S.D. Tex. 2012) (Texas law); *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 817-18 (D.S.C. 2011); *see also Products Liability* § 50.03A[3], at 50-58.1 ("Many – but not all – states require the plaintiff to prove the existence of a safer alternative design at the time of manufacture to prevail in defective design cases [involving prescription drugs].") (footnote omitted).

Considering the stringent standards applicable to design-defect claims involving prescription drugs, it is not surprising that "[f]ailure to instruct or warn is the major basis of liability for manufacturers of prescription drugs." Restatement (Third) of Torts: Products Liability § 6 cmt. d. Cases such as this one, in which an injured patient obtains a damages judgment against a drug manufacturer based on a products liability theory other than failure to warn, are exceedingly rare.[12] They certainly do not recur with sufficient frequency to warrant this Court's review of the question whether federal law preempts the underlying theory of liability.

Moreover, petitioner could have avoided liability altogether by showing that sulindac was "unavoidably unsafe" under comment k, but, after relying on comment k for more than a year, it inexplicably withdrew that defense on the eve of trial. The question presented here thus both lacks national import and arises in an apparently unprecedented setting, where the manufacturer essentially threw in the towel before trial on its main defense – a defense that is frequently successful for pharmaceutical manufacturers in cases nationwide.

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[12] Indeed, we are aware of no instance in which an FDA-approved drug was withdrawn from the market as a result of a state tort verdict (let alone a verdict on a design-defect claim).

2. Sulindac is not an essential drug, and petitioner presented no contrary evidence

As the district court stated, "[t]he FDA has recommended that five NSAIDs be removed from the market due, in part, to their risk of SJS/TEN as demonstrated by adverse event reports (sometimes fewer than 15)." App. 46a. "From 1980 to 1997, the FDA's adverse event reporting database – which collects spontaneous reports of drug side effects from doctors, manufacturers, patients, etc. – received *89 reports* of SJS/TEN attributed to sulindac, more than the number of reports for any other NSAID on the market and all but four drugs of any kind." App. 44a (emphasis added). A report prepared by petitioner's own dermatology expert showed that "sulindac may have had the highest SJS/TEN reporting rate among NSAIDs from 1980 to 1997." App. 17a-18a. In addition, there is no evidence that sulindac "is more or less risky than other NSAIDs with regard to various other [non-skin-related] known side effects." App. 45a. Ms. Bartlett's experts thus "opine[d] that sulindac's overall risk/benefit profile was unfavorable for marketing." App. 12a. Petitioner did not call a single witness to counter that evidence. *See* App. 5a.

Petitioner asserted that Ms. Bartlett was required to present evidence of a safer alternative *product*, despite the absence of any "authority for such a requirement." App. 64a. Although "not required to do so," Ms. Bartlett "presented considerable evidence for the jury to consider with regard to safer alternative products": "her experts testified that sulindac is part of two NSAID groups . . . believed to have a greater risk of SJS/TEN than other NSAIDs, with no greater benefits." App. 65a. Other NSAIDs "have no risk of SJS/TEN" and "are equally effective in treat-

ing conditions like shoulder pain (for which Bartlett took sulindac)." *Id.* The district court explained that, under New Hampshire Supreme Court authority, "it was up to the jury . . . to determine how much weight (if any) to give Bartlett's evidence regarding safer alternative products." App. 66a.

3. The district court cases cited by petitioner do not justify this Court's review

Petitioner cites (at 19) a list of nine district court decisions that it claims decided the question presented differently from the First Circuit. That claim is incorrect, and those cases provide no reason to grant review.

At the outset, each of those cases was filed before *PLIVA*, and the plaintiffs' principal theory of liability generally involved an alleged failure to warn.[13] In one case, the plaintiff failed even to oppose the defendants' motion to dismiss in light of *PLIVA*.[14] In the others, the courts rejected the plaintiffs'

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[13] *See Eckhardt*, 858 F. Supp. 2d at 798 ("[T]his is primarily a failure to warn case."); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-2226-DCR, 2012 WL 718618, at *3 n.7 (E.D. Ky. Mar. 5, 2012) ("the plaintiffs have merely repackaged their failure-to-warn claims"); *Aucoin v. Amneal Pharm., LLC*, Civil Action No. 11-1275, 2012 WL 2990697, at *1-*2 (E.D. La. July 20, 2012); *Johnson v. Teva Pharm. USA Inc.*, No. 2:10 CV 404, 2012 WL 1866839, at *1-*2 (W.D. La. May 21, 2012); *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 WL 368675, at *1 (D. Vt. Feb. 3, 2012); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 484-85 & n.7 (E.D.N.Y. 2012); *Gross*, 825 F. Supp. 2d at 658; *Stevens v. PLIVA, Inc.*, Civil No. 6:10-0886, 2011 WL 6224569, at *2 (W.D. La. Nov. 15, 2011), *report and recommendation adopted*, 2011 WL 6224556 (W.D. La. Dec. 2, 2011); *see also In re Fosamax (Alendronate Sodium) Prods. Liab. Litg. (No. II)*, Civil No. 08-008, 2011 WL 5903623, at *9 (D.N.J. Nov. 21, 2011).

[14] *See Pamidronate*, 842 F. Supp. 2d at 481.

efforts to avoid *PLIVA*'s preemption holding by re-characterizing their warning claims as non-warning claims. Several of the courts concluded that the plaintiffs had failed to plead facts that would give rise to a plausible claim for defective design.[15] In another case, the district court held that the applicable state law did not even recognize a design-defect claim.[16] As those pre-*PLIVA* cases work their way through the judicial process, the likelihood of these issues recurring will become even more remote.

To be sure, in several of the cases that petitioner cites, the district courts stated that federal law preempts design-defect claims. But those claims were premised on an alleged failure to *change* the drug's design, and therefore were fundamentally different from Ms. Bartlett's claim here. Under New Hampshire law, Ms. Bartlett did not need to assert, and did not assert, that the design of sulindac needed to be changed. In contrast, four of the cases that petitioner cites arose in states that require the plaintiff to plead and prove the existence of a reasonable alternative design that the defendant manufacturer

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[15] *See Fullington v. PLIVA, Inc.*, No. 4:10CV00236 JLH, 2011 WL 6153608, at *5 (E.D. Ark. Dec. 12, 2011) ("While products liability law in Arkansas encompasses claims for relief other than failure to warn, Fullington has not adequately pled any such claims."), *cited in* Pet. 21; *Aucoin*, 2012 WL 2990697, at *10 ("[I]nstead of alleging either of the elements for a design defect claim, Plaintiff has merely recited the elements of the cause of action."); *Lyman*, 2012 WL 368675, at *4 n.4 (plaintiffs "have not adequately pled claims for . . . design defects"); *Pamidronate*, 842 F. Supp. 2d at 484 n.7 ("Plaintiffs' allegations of design defect also fail because they are not supported by factual allegations in the Complaint").

[16] *See Gross*, 825 F. Supp. 2d at 658.

could have adopted.[17] In other cases, the courts understood the plaintiffs' claims to be premised on alleged failures to improve a drug's design.[18]

Having concluded that the gravamen of the plaintiffs' claims in those cases was the failure to change the drug's design, the courts determined that compliance with federal and state law was impossible. Thus, for example, the district court in *Johnson* concluded that, because (in the court's view) federal law "prevented the Generic Defendants from altering unilaterally the design of the drug itself," the plaintiff could not "show that the Generic Defendants could have used an alternative design," as required by Louisiana law. 2012 WL 1866839, at *4, *5 n.13.

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[17] *See Eckhardt*, 858 F. Supp. 2d at 801 ("For a plaintiff to prevail on a design defect claim under Texas law, he 'must prove that there is a safer alternative design.' 'In the absence of a safer alternative, a product is not unreasonably dangerous as a matter of law.'") (quoting *Brockert v. Wyeth Pharm. Inc.*, 287 S.W.3d 760, 769 (Tex. App. 2009)) (footnote omitted); *Johnson*, 2012 WL 1866839, at*4-*5 & n.13 (applying Louisiana statute requiring proof of an alternative design); *Aucoin*, 2012 WL 2990697, at *10 (same); *Stevens*, 2011 WL 6224569, at *2 (same).

[18] *See Lyman*, 2012 WL 368675, at *4 ("[plaintiffs'] claims that the Generic Defendants' metoclopramide should have been designed . . . differently are preempted as well") (citations omitted); *Fosamax*, 2011 WL 5903623, at *6 ("Here, plaintiffs allege that Generic Defendants' alendronate sodium should have been designed differently to comply with state tort law."); *Pamidronate*, 842 F. Supp. 2d at 484 ("federal law preempts state laws imposing a duty to change a drug's design on generic drug manufacturers"), 485 ("[b]ecause [the implied-warranty] cause of action is founded on the argument that pamidronate should have been designed differently, it fails").

The court therefore held that the plaintiff's "design defect claims" were "preempted." *Id.* at *4.[19]

In short, those district court decisions addressed a fundamentally different preemption issue from the one addressed by the First Circuit: they concerned whether an asserted state-law duty to change the design of a generic drug conflicted with federal law. This case does not present that question because it does not involve such a state-law duty.

C. Petitioner Has Not Demonstrated The Suitability Of This Case As A Vehicle To Decide The Question Presented

In all events, petitioner's withdrawal of its comment k defense makes this case an especially poor vehicle in which to address the question presented or for this Court's decision to apply beyond the unusual facts of this case. Petitioner voluntarily withdrew its comment k defense. The jury therefore could not premise liability on whether petitioner provided an adequate warning of sulindac's risks, making this case unlike the district court cases in which the primary theory of liability was failure to warn. In addition, if petitioner had not abandoned its comment k defense, it could have argued that Ms. Bartlett was required to show the existence of an alternative design for sulindac – to show that the drug is not "unavoidably unsafe." But, because it withdrew its primary defense (which was the premise for that argument), and because New Hampshire law does not otherwise require proof of a feasible alternative

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[19] *Accord Aucoin*, 2012 WL 2990697, at *9 n.101 (citing *Johnson*); *Eckhardt*, 858 F. Supp. 2d at 801-02 (defendants "were not free to unilaterally pursue a safer alternative design in order to comply with state law," and "[t]he design defect claim is thus preempted").

design, the jury's verdict of liability did not depend in any way on any alleged failure by petitioner to change the design of its product.

Impossibility preemption requires a careful "compar[ison of] federal and state law." *PLIVA*, 131 S. Ct. at 2573. Accordingly, even if this Court were to consider the question whether federal law preempts design-defect claims involving generic manufacturers, it should do so in a case in which the applicable state law follows the majority approach and in which the drug manufacturer has presented a defense typical of litigation in this area (as opposed to no defense case at all). Petitioner has offered no reason why the question it seeks to present would not recur in a future case that would present a more suitable vehicle for this Court's review.

II. THE COURT OF APPEALS' DECISION IS CORRECT AND DOES NOT CONFLICT WITH *PLIVA*

The First Circuit correctly concluded that federal law does not preempt New Hampshire law in this case. Neither the Federal Food, Drug, and Cosmetic Act nor the Hatch-Waxman Amendments contains an express preemption provision for prescription drugs, and petitioner does not argue that federal law preempts the relevant field. Rather, petitioner's claim is that New Hampshire law is preempted because it "directly conflict[s]" with federal law. *PLIVA*, 131 S. Ct. at 2577 (internal quotations omitted). Such a conflict can arise when "it is impossible for a private party to comply with both state and federal requirements" or when "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Sprietsma*

v. Mercury Marine, 537 U.S. 51, 64 (2002) (internal quotations omitted).

In this Court, petitioner does not assert – and therefore has forfeited – any claim that "recognition of [Ms. Bartlett's] state tort action creates an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Levine*, 555 U.S. at 563-64 (internal quotations omitted); *cf. PLIVA*, 131 S. Ct. at 2581 n.7 (noting that purposes-and-objectives preemption was not argued there). Instead, petitioner's claim is that a direct conflict exists in this case because "it is *impossible* for [petitioner] to comply with both state and federal requirements." *PLIVA*, 131 S. Ct. at 2577 (emphasis added; internal quotations omitted); *see* Pet. 23, 25. The court of appeals properly rejected that argument.

A. The Court Of Appeals Correctly Concluded That Compliance With Federal And State Law Is Not Impossible In This Case

Analysis of impossibility preemption requires the court "to compare federal and state law." *PLIVA*, 131 S. Ct. at 2573. The first step in that analysis is to "identify[] the state tort duties and federal . . . requirements applicable to the [m]anufacturer[]." *Id.*

1. New Hampshire law imposes strict, but not automatic, liability on sellers of unreasonably dangerous products

New Hampshire law imposes strict liability on manufacturers of products that are "unreasonably dangerous to the user." *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 846 (N.H. 1978) (internal quotations omitted). New Hampshire has "adopted the doctrine of strict liability of manufacturers for product defects in section 402A (1) of the *Restatement*

(Second) of Torts." *Kelleher*, 891 A.2d at 492. Under the Restatement, "'[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer.'" *Id.* (quoting Restatement (Second) of Torts § 402A(1)) (emphasis omitted).

To determine whether a product is "unreasonably dangerous" – and therefore "defective" – New Hampshire courts ask whether the product is "'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.'" *Bellotte v. Zayre Corp.*, 352 A.2d 723, 725 (N.H. 1976) (quoting Restatement (Second) of Torts § 402A cmt. i). "Whether a product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer is," in turn, "determined by the jury using a risk-utility balancing test." *Price v. BIC Corp.*, 702 A.2d 330, 332 (N.H. 1997).

Under that risk-utility balancing test, the trier of fact weighs the product's risks and benefits to determine whether "'the magnitude of the danger outweighs the utility of the product.'" *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001) (quoting W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* 699 (5th ed. 1984)); *see also id.* (discussing factors relevant to that inquiry). If a product's risks outweigh its benefits, then the product "is defective as designed." *Id.*

To establish liability under New Hampshire law, a plaintiff need not prove the existence of a reasonable alternative design that the manufacturer could have adopted. *See Kelleher*, 891 A.2d at 492 ("[T]he plain-

tiff is not required to present evidence of a safer alternative design."); *Vautour*, 784 A.2d at 1182-84; App. 58a-61a. The term "design defect" is thus a misnomer as applied to New Hampshire law. The question in New Hampshire is simply whether the product's risks outweigh its benefits; if so, the product is unreasonably dangerous, and the seller is subject to liability for injuries resulting from use of the product. That is so regardless of whether the design is otherwise "defective" or could be improved.

Applying those principles of New Hampshire law, the properly instructed jury in this case found that sulindac's risks outweighed its benefits, making it a defective product unreasonably dangerous to consumers. *See* App. 30a.

2. Nothing in federal law precluded petitioner from complying with New Hampshire law

Assuming federal law does not permit manufacturers of generic drugs to alter the design of their products, it does not require them to manufacture and sell those products. *See* App. 10a-11a.[20] Petitioner's "decision to make [sulindac] and market it in New Hampshire is wholly its own." App. 11a. Because petitioner "could independently do under federal law [anything] state law require[d] of it," the court of ap-

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[20] FDA regulations provide that "FDA will withdraw approval of an application or abbreviated application if the applicant requests its withdrawal because the drug subject to the application or abbreviated application is no longer being marketed." 21 C.F.R. § 314.150(c). If a manufacturer is "the sole manufacturer" of a drug that is "life supporting, life sustaining, or intended for use in the prevention of a serious disease or condition" – a category that does not include sulindac – it must notify FDA at least six months before discontinuing manufacture of the drug. *Id.* § 314.81(b)(3)(iii)(1).

peals properly rejected petitioner's defense of impossibility preemption. *PLIVA*, 131 S. Ct. at 2579.

B. The Court Of Appeals' Decision Does Not Conflict With This Court's Decision In *PLIVA*

1. There is no conflict between this case and *PLIVA* because *PLIVA* involved a different state-law duty

The injured patients in *PLIVA* brought tort claims against manufacturers of the generic drug metoclopramide. *See* 131 S. Ct. at 2572. They asserted that the manufacturers "were liable under state tort law (specifically, that of Minnesota and Louisiana) for failing to provide adequate warning labels" – specifically, labels that adequately warned of the risk of developing tardive dyskinesia. *Id.* at 2573.

This Court began its preemption analysis by "identifying the state tort duties and federal labeling requirements applicable to the Manufacturers." *Id.* The parties did "not dispute that," under the facts alleged by the plaintiffs, "state law required the Manufacturers to use a different, safer label." *Id.* at 2574; *see id.* at 2577 (state law "required the Manufacturers to use a different, stronger label than the label they actually used"), 2578 ("[S]tate law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide."). The parties did, however, dispute whether federal law permitted the generic manufacturers to strengthen the warnings on their drug labels. *See id.* at 2574-77. Resolving that dispute, this Court held that federal law "prevented the Manufacturers from independently changing their generic drugs' safety labels." *Id.* at 2577; *see id.* at 2578 ("Federal law . . . demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels.").

The Court then "compare[d]" those requirements of "federal and state law" and concluded that it was "impossible for [the manufacturers] to comply with both [the] state and federal requirements." *Id.* at 2573, 2577 (internal quotations omitted). "The question for 'impossibility,'" the Court explained, "is whether the private party could independently do under federal law what state law requires of it." *Id.* at 2579. "If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id.* at 2578. Consequently, "it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same," *id.*, and the plaintiffs' claims were therefore preempted by federal law, *see id.* at 2581.

This case is fundamentally different from *PLIVA*. In *PLIVA*, state law required the generic manufacturers to do something that federal law prohibited – namely, change the labels of their drugs. Here, by contrast, nothing in New Hampshire law requires petitioner to change sulindac's design, and nothing in federal law prohibits petitioner from declining to sell the drug. A straightforward application of this Court's analysis in *PLIVA* thus compels the conclusion reached by the lower courts in this case – petitioner's defense of impossibility preemption lacks merit.

2. New Hampshire law did not require petitioner to perform any act that federal law prohibits

Petitioner argues that the court of appeals' decision is inconsistent with *PLIVA* because, in that case, the manufacturers could presumably have avoided liabil-

ity for failure to warn by declining to sell metoclopramide in Minnesota and Louisiana. According to petitioner, "[w]ere the holding below correct," *PLIVA* "would have come out the other way." Pet. 3.

Not so. In *PLIVA*, state law *required* the defendant to do something that federal law prohibited it from doing. State law required the manufacturers "to attach a safer label to their generic metoclopramide." 131 S. Ct. at 2578. Suspending sales of the drug might have been an indirect means of avoiding future tort liability for failing to comply with the duty to warn, but it was not the act required by the state-law duty. When, as in *PLIVA*, a holding under state law would obligate a party to take an action (such as changing the label for its product) that federal law prohibits, that claim is preempted, even if the party could avoid liability by removing its product from the market. Here, by contrast, the holding under New Hampshire law did not require petitioner to perform any act that federal law prohibits it from doing independently.

Moreover, as petitioner concedes, this Court in *PLIVA* did not in fact address the effect on preemption analysis of a manufacturer's ability to remove its product from the market. *See* Pet. 20; *PLIVA*, 131 S. Ct. at 2573-82. Although, as petitioner notes (at 3-4, 10-11, 20), the Eighth Circuit had relied on that ability as an additional reason supporting its conclusion that compliance with both federal and state law was possible, *see* 588 F.3d at 608-11, the plaintiffs did not raise the issue in their merits brief in this Court, *see* Br. for Resps. Gladys Mensing and Julie Demahy, *PLIVA*, *supra* (Nos. 09-993 et al.) (U.S. filed Feb. 23, 2011). As petitioner also observes (at 4, 13, 20), the plaintiffs in *PLIVA* argued in a rehearing petition,

which this Court summarily denied, *see PLIVA, Inc. v. Mensing*, 132 S. Ct. 55 (2011), that the manufacturers could have avoided liability under state law by suspending sales of their drugs. But that summary denial of rehearing lacks precedential force.[21] In addition, petitioner here did not raise in the court of appeals the alleged import of the denial of rehearing in *PLIVA*, making its criticism of the First Circuit for supposedly overlooking the point all the more unwarranted.

C. Petitioner's Other Criticisms Of The First Circuit's Decision Lack Merit

Petitioner claims that the First Circuit's decision "would render conflict pre-emption largely meaningless." Pet. 28, 31 (internal quotations omitted). But, as noted above, a regulated party's ability to stop selling its product does not negate preemption where it provides only an indirect means to avoid liability for failing to comply with an affirmative state-law duty. Under the law and facts of this apparently unprecedented case, however, no affirmative duty was imposed on petitioner that federal law prohibited it from fulfilling.

Moreover, the First Circuit's reasoning on this point applies only to impossibility preemption – the only form of conflict preemption addressed in *PLIVA*. *See* 131 S. Ct. at 2581 n.7. Federal law continues to preempt state tort suits that frustrate the accomplishment of Congress's purposes and objectives, regardless of whether the defendant could comply

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[21] *Cf. Fernandez v. Chardon*, 681 F.2d 42, 51 n.7 (1st Cir. 1982) ("surely the denial of a petition for rehearing can have no greater precedential effect than the denial of a petition for certiorari, which is to say none"), *aff'd sub nom. Chardon v. Fumero Soto*, 462 U.S. 650 (1983).

with state law by suspending sales of its product. *See, e.g., Geier v. American Honda Motor Co.*, 529 U.S. 861, 881-82 (2000).[22]

Petitioner also mischaracterizes (at 4, 28) the First Circuit's decision as adopting a "so-called 'choice of reaction' thesis," under which state tort duties are not preempted because the defendant can pay any damages judgments and continue to comply with federal law. But that "thesis" assumes that the defendant will continue *to violate state law*, thus the need to continue to "'pay damages to successful tort plaintiffs.'" Pet. 4 (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1542 (D.C. Cir. 1984)). The First Circuit's decision, by contrast, is premised on the conclusion that petitioner can simultaneously *comply* with state and federal law: it can avoid future liability for selling an unreasonably dangerous product without violating federal law, which does not require petitioner to sell sulindac.[23]

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[22] Petitioner does not raise purposes-and-objectives preemption in this Court and therefore has waived it. This case accordingly provides no opportunity to consider whether the mere approval by the FDA of an application to market a generic drug preempts strict-liability claims arising from injuries caused by that product. In all events, the First Circuit correctly concluded that, under *Levine* and *PLIVA*, state tort suits against drug manufacturers do not present an unacceptable obstacle to Congress's purposes, when (as here) compliance with federal law and the holding under state law is possible. *See supra* pp. 6-7.

[23] In all events, petitioner's assertion (at 30) that this Court has "decisively rejected *Ferebee*'s claim that state-law damage awards do not constitute state regulatory 'requirements' that conflict with federal law" is incorrect. The cases that petitioner cites – *Riegel*, 552 U.S. at 324, and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion) – involved the interpretation of express-preemption provisions, not the application of implied conflict preemption. In the conflict-preemption

D. Petitioner's Position Depends On A Mischaracterization Of New Hampshire Law

1. New Hampshire law does not require petitioner to change the design of its drug

Petitioner asserts that New Hampshire law imposes on it a duty to change the design of its generic sulindac to make the drug safer. *See* Pet. 23, 25. That misstates New Hampshire law, which imposes liability for "'*sell[ing]*'" an unreasonably dangerous product. *Kelleher*, 891 A.2d at 492 (quoting Restatement (Second) of Torts § 402A(1)) (emphasis added). New Hampshire does not require proof of a safer alternative design, *see id.*, meaning that a seller of an unreasonably dangerous product is liable for resulting injuries regardless of whether it could have redesigned the product to avoid the harm. As the district court explained, petitioner "was not held liable for failing to change sulindac's design; it was held liable for selling an unreasonably dangerous product." App. 72a.[24]

2. Design-defect and failure-to-warn claims are distinct under New Hampshire law

Petitioner also erroneously asserts that "failure-to-warn and design-defect claims are one and the same" because, "under *comment k*, design-defect liability is

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context, this Court has recognized, but not resolved, the question whether the incidental regulatory effects of state tort judgments create preemptive "obstacle[s]" to the accomplishment of federal purposes. *See Geier*, 529 U.S. at, 882. Regardless of the resolution of that question, petitioner cannot dispute that it is *possible* to pay the judgment to Ms. Bartlett without violating federal law.

[24] *See also* App. 165a ("[a]ssuming . . that [federal law] would prevent the defendants from changing Sulindac's design, that would not conflict with the state law underlying the Bartletts' non-failure-to-warn claims" because "[t]hose claims allege that the defendants violated state law by distributing a product that was defectively designed" and "not fit for its intended use").

predicated on the absence of an adequate warning." Pet. 23-24 (footnote omitted). That, too, misstates New Hampshire law. In New Hampshire, failure to warn is a basis for liability separate and distinct from liability for selling an unreasonably dangerous product.[25] The existence of an adequate warning can in some cases be a factor that a jury applying New Hampshire's risk-utility balancing test can consider in determining whether a product is unreasonably dangerous. *See Vautour*, 784 A.2d at 1182; App. 36a-37a. But the basis for liability remains the sale of an unreasonably dangerous product. *See LeBlanc*, 688 A.2d at 562. As the district court explained, "[t]he warning was not sulindac's defective condition; the unreasonable danger was." App. 67a.[26]

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[25] *See LeBlanc v. American Honda Motor Co.*, 688 A.2d 556, 562 (N.H. 1997) ("The plaintiff's design defect and failure to warn claims are separate. Under the design defect claim, the issue is whether the [automobile] was defective *in that* it had a fixed rear axle and whether that defect made the product unreasonably dangerous. The issue in the failure to warn claim, in contrast, is whether the danger inherent in the [automobile] was or could have been made reasonable by the issuance of adequate warnings.").

[26] In *Kurns v. Railroad Friction Products Corp.*, 132 S. Ct. 1261 (2012), the Court concluded that a claim that a manufacturer of asbestos-containing locomotive parts failed to warn of the risks of asbestos was "directed at the equipment of locomotives" and therefore fell within the broad preempted field of the Locomotive Inspection Act, as interpreted in *Napier v. Atlantic Coast Line Railroad Co.*, 272 U.S. 605 (1926). *Kurns*, 132 S. Ct. at 1268. But even if a failure-to-warn claim necessarily "alleges that the product itself is unlawfully dangerous," *id.*, that does not mean that a design-defect claim necessarily alleges that the product lacks "an adequate warning," Pet. 24. In fact, as explained in the text, design-defect liability does *not* necessarily turn on the adequacy of warnings. Moreover, petitioner's withdrawal of its comment k defense took the adequacy of sulindac's

3. Petitioner's waiver of its comment k defense precluded the jury from finding liability based on an inadequate warning

More fundamentally, petitioner's effort to equate the claim that was tried in this case with the failure-to-warn claim at issue in *PLIVA* disregards the law of the case. In the district court, petitioner "voluntarily withdrew" before trial its comment k defense. *See* App. 36a, 60a-61a. With petitioner's "'comment k' defense out of the case, the adequacy of sulindac's warning . . . was no longer an issue for trial." App. 36a. The court accordingly "instructed the jury *(at [petitioner]'s request)* that Mutual's 'conduct in responding' to sulindac's safety risks, which included any failure to change its warning, was 'not relevant to this case, and you should put [it] out of your mind.'" App. 74a (emphasis added; alterations in original).

The district court also "ruled that warning-related evidence could be admitted at trial [only] for a limited purpose: if the jury found that sulindac's risks outweighed its benefits, then it could consider whether the warning – regardless of its adequacy – reduced those risks or increased those benefits to such an extent that it eliminated the unreasonable danger. In other words, the warning could operate only to [petitioner]'s benefit." App. 37a. Furthermore, Ms. Bartlett did not argue to the jury that a lack of an adequate warning rendered sulindac

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warning out of this case entirely as a basis for liability. As the district court explained, the warning was not in the case "in the sense that Mutual could have been held liable for failing to change it"; rather, Ms. Bartlett had to "prove that sulindac was unreasonably dangerous *despite* its warning, not *because* of it." App. 74a (internal quotations omitted).

unreasonably dangerous; rather, her "sole" theory at trial centered on sulindac's propensity to cause SJS/TEN. App. 68a. In short, the trial record – and, in particular, petitioner's withdrawal of its comment k defense – forecloses petitioner from arguing now that liability in this case was "predicated on the absence of an adequate warning." Pet. 24.

In all events, any dispute about the content of state law would not warrant this Court's review. *See Propper v. Clark*, 337 U.S. 472, 486-87 (1949). In *PLIVA*, the meaning of state law was "undisputed," 131 S. Ct. at 2573, and this Court's analysis focused on the requirements imposed by federal law and their implications for preemption, *see id.* at 2574-82. Likewise, in *Levine*, the Court took it as a given that state law required Wyeth to provide a stronger warning for its drug Phenergan, and the Court's opinion centered on the content of federal law. *See* 555 U.S. at 568-81. The Court should not grant review here simply to review the First Circuit's understanding of New Hampshire law, particularly when that state's products-liability law differs from the law of many other states and petitioner's own litigation decision uniquely removed from the jury's consideration the one defense typically invoked by defendants.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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REPLY BRIEF

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IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the First Circuit

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INTRODUCTION

The First Circuit recognized that it created a "split in the lower courts" and practically begged this Court to provide "a decisive answer" on this "question of exceptional importance." App. 10a-11a. Respondent now tries to obscure that conflict by pretending that the stop-selling theory is good for one claim and one state only. She is wrong. The Fifth Circuit recently rejected this same theory of design-defect liability *for the second time*, just like the Sixth and Eighth Circuits rejected identical stop-selling arguments before it.

Indeed, this case demonstrates in spades that there is no plausible basis for distinguishing design-defect claims from failure-to-warn claims for purposes of the stop-selling theory. Consistent with comment k, the instructions in this case make clear that the jury's verdict hinged on precisely what *Mensing* barred: a finding that petitioner's FDA-mandated warnings were inadequate. More broadly, the First Circuit conceded that Hatch-Waxman's sameness mandate applies equally to design-defect and failure-to-warn claims, App. 10a, *and* that the stop-selling theory could be deployed equally against both claims. App. 11a. Given the record and those concessions, the stop-selling theory can be right only if *Mensing* is wrong—which is why the First Circuit effectively challenged this Court to reconsider that decision. *Id.*

That is not how our legal system works. The First Circuit may not like *Mensing*, but it had no business defying this Court and daring it to say that *Mensing* meant what it said. This Court should grant the petition and summarily reverse.

ARGUMENT

A. The First Circuit Erred By Creating A Circuit Split.

Respondent argues "[t]here is no circuit conflict" because this case "is the first ... and only" post-*Mensing* decision addressing "theories other than failure to warn." BIO 7. That is demonstrably false, as the First Circuit conceded, App. 11a, and the Fifth Circuit's post-remand decisions in *Demahy* underscore.

Demahy involved myriad claims against generic manufacturer Actavis, including for design defect. Pet. 11. And respondent now acknowledges that the Fifth Circuit considered *Mensing*'s scope on remand and rejected that lawsuit *in its entirety*: It "remanded for entry of judgment in favor of [Actavis]," including on design defect. BIO 11 (citing *Demahy v. Actavis, Inc. [Demahy I]*, 650 F.3d 1045 (5th Cir. 2011)).

Demahy's most telling feature, however, is not what respondent acknowledges; it is what she fails to disclose. After the district court entered judgment for Actavis, Demahy appealed—asserting (like respondent, BIO 10-11) that the original *Demahy* appeal involved only failure-to-warn claims, and that the district court therefore misconstrued the mandate as foreclosing design-defect liability. Indeed, citing this decision, Demahy argued that her stop-selling theory of design-defect liability survived *Mensing*. Notice of Supp. Auth., *Demahy v. Schwarz Pharma, Inc. [Demahy II]*, No. 11-31073, at 2 (5th Cir. filed May 3, 2012) ("*Bartlett* ... determined that since Mutual could decide not to manufacture an unreasonably dangerous drug, [federal law] would

permit the states to impose liability for continuing to sell [it].").

The Fifth Circuit decisively rejected those claims before respondent filed her BIO. *Demahy II*, 2012 WL 5261492 (Oct. 25, 2012). It explained that the prior *Demahy* courts considered design-defect and failure-to-warn claims materially indistinguishable, and therefore affirmed the trial court's conclusion that *Demahy I* rejected her design-defect claim pursuant to *Mensing*. *Id.* *5. It then held in the alternative that federal law preempts the stop-selling theory anyway:

> Post-*Mensing* ... courts have specifically held ... that state-law tort claims against generic drug manufacturers, including design defect claims, are preempted after *Mensing*. Thus, although unnecessary for the disposition [given our alternative holding regarding *Demahy I*], we are persuaded that Demahy's design defect claim would be preempted.

Id. *6 (citations and footnotes omitted).

These events fatally undermine respondent's rejection of the First Circuit's admission that there is a "split in the lower courts [which] needs a decisive answer." App. 11a. The Fifth Circuit has rejected respondent's stop-selling theory *twice*. And it is not alone. The Sixth and Eighth Circuits likewise have rejected it. Pet. 1-2, 19-21 (discussing *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011); *Mensing v. Wyeth*, 658 F.3d 867 (8th Cir. 2011)).

Respondent downplays those decisions by claiming they rejected this theory only for failure-to-

warn claims. BIO 9-11. That is no distinction, as the First Circuit acknowledged by conceding that Hatch-Waxman's sameness mandate applies equally to generic design. App. 10a ("[Petitioner] cannot legally make sulindac in another composition."); *see also Mensing*, 131 S. Ct. at 2574 n.2 (explaining that generic drugs must be "identical in active ingredients, safety, and efficacy"). Yet apart from declaring that *Wyeth* created a "general no-preemption rule" that might lead this Court to reconsider the stop-selling theory "despite what [it] made of similar arguments in [*Mensing*]," App. 10a-11a—a suggestion even respondent refuses to defend—the court did not even try to explain why federal law would preempt respondent's stop-selling theory in the warnings context but not the design context. Indeed, it admitted there is no such explanation. *Id.* ("[A] generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug.").

Respondent nonetheless seeks to reconcile these decisions by asserting that failure-to-warn claims are based on a duty *to change* product warnings (conduct federal law bars), whereas design-defect claims are based on a duty *to stop selling* the product (conduct federal law permits). BIO 25-26. That is just wordplay. Saying that failure-to-warn liability is imposed because a manufacturer *failed to change* the warning is just the flipside of saying that liability is imposed because the manufacturer *sold a product with a defective warning*. The manufacturer's duty is "to adequately and safely label [its] products" for sale, *Mensing*, 131 S. Ct. at 2577, so it has two options: Change the label or stop selling it.

That is just like respondent's design-defect claim, which asserted petitioner *sold a product with a defective design*. State law offered the same two options: Change the design or stop selling it. And because Hatch-Waxman equally precludes labeling *and* design changes, state law *in both cases* seeks equally to impose liability for selling products that manufacturers cannot lawfully "fix."

Mensing's rejection of the stop-selling theory thus cannot be limited to failure-to-warn claims. Indeed, its logic extends *to every claim*, because every products case begins *with a sale*. Without one, there is no basis to sue—and no need for a preemption defense. But because plaintiffs can *always* argue that defendants were permitted to stop selling their products, the stop-selling rationale would prevent defendants from *ever* asserting conflict preemption successfully. *In re Darvocet*, MDL No. 2226, 2012 WL 718618, *3 (E.D. Ky. Mar. 5, 2012) (rejecting stop-selling theory because it "could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct"); *see also Mensing*, 131 S. Ct. at 2579 ("We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless.").

Were this theory viable, *Mensing* thus would have *rejected* preemption; as the First Circuit conceded, generic manufacturers can avoid failure-to-warn *and* design-defect liability by suspending sales. App. 11a. Respondent nonetheless seeks to cabin the stop-selling rationale to design-defect cases by claiming that it is "an indirect means" of complying with state

labeling duties, but a direct means of complying with state design requirements. BIO 26; *id.* 27. That hinges on the same fiction addressed earlier—that the underlying state-law duties are structurally distinct (they are not). But the argument fails even on its terms. Federal law's preemptive force does not turn on whether the stop-selling end-run is "direct" or "indirect." If the Supremacy Clause means anything, it means states cannot require companies *to violate federal law as a precondition to doing business within their borders.* That is why the other circuits and scores of district courts have rejected the stop-selling theory.[1]

It also is why this Court long ago rejected the "choice-of-reaction" thesis, which held that federal law does not preempt state tort claims because defendants can *both* sell their products *and* pay damages. Pet. 28-31 (explaining the conflict with *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)). Respondent says these cases are irrelevant because they presume "the defendant will continue to violate state law [by selling products], thus the need to continue to pay damages." BIO 28 (quotation omitted). But that is the point: These cases held that state tort law cannot effectively require companies to violate federal law if they want to sell their products

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[1] Respondent distinguishes the district court cases *on state-law grounds*, asserting that several arose in jurisdictions requiring proof of a feasible alternative design. BIO 17-18. Whatever merit that independent state-law defense may have had, these decisions considered and rejected the stop-selling theory under *Mensing*. *See* Pet. 19-21.

free from liability. *Cipollone*, 505 U.S. at 521 (quotation omitted); *see also Riegel*, 552 U.S. at 324.[2]

At bottom, the First Circuit rightly acknowledged that it had created a "split in the lower courts." App. 11a. Its decision conflicts *both* with the Fifth, Sixth, and Eighth Circuits' recognition that *Mensing* forecloses the stop-selling theory, *and* with the line of cases culminating in *Cipollone* and *Riegel*.

B. The First Circuit's Decision Warrants Review And Summary Reversal.

The First Circuit's outlier decision undeniably warrants review. The appellate court recognized this case presents "a question of exceptional importance," App. 8a, and specifically called for "a decisive answer from [this Court]." App. 11a. Respondent's lawyers agreed. They hailed the decision as "potentially huge" because it "establishes that *Mensing* ... has no relation to a product defect case." S. Hsieh, *First Circuit Gives Plaintiffs' Lawyers Opening In Drug Suits*, NEW ENGLAND IN-HOUSE (June 30, 2012), http://newenglandinhouse.com/2012/07/13/1st-circuit-gives-plaintiffs-lawyers-opening-in-drug-suits/ (visited Nov. 12, 2012). And they candidly admitted the decision sows "fertile ground for an appeal." T. Buckland, *Plaistow Woman's Lawsuit Could End Up*

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[2] It is irrelevant that *Cipollone* and *Riegel* involved express-preemption clauses. BIO 28 n.23. Those provisions preempted state-law requirements *that conflicted with federal law*, and the cases held that conflict could not be avoided by conditioning product sales on paying damages. *Riegel*, 552 U.S. at 323-24 (describing cases).

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Respondent now runs from those concessions—asserting that design-defect claims are so "difficult to prove," BIO 12, and New Hampshire law so exotic, BIO 12-13, 29-32, that the question presented will "not recur with sufficient frequency to warrant ... review." BIO 14. Not so.

As petitioner explained (Pet. 23-25), the First Circuit held (App. 7a), and respondent concedes (BIO 4), New Hampshire has adopted comment k—like most other states, *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1077 n.41 (2011). That eliminates any distinction between failure-to-warn and design-defect claims for preemption purposes, because comment k precludes design-defect liability so long as pharmaceutical products are "'accompanied by proper directions and warning.'" BIO 4 (quoting *Restatement (Second) of Torts* § 402A, cmt. k). New Hampshire design-defect liability thus hinges on challenging the adequacy of product warnings, as it does virtually everywhere else.

The jury instructions illustrate this point:

> If you determine that Sulindac was unreasonably dangerous *and that a warning was not present and effective to avoid that unreasonable danger*, then you must find [respondent] has proven this element of her claim, a defect in design. However, if you determine that sulindac was unreasonably dangerous, *but that a warning was present and effective to avoid that unreasonable danger*, then you must find for [petitioner].

Supp. App. 3a (emphases added). Accordingly, there is no question the the jury's verdict depended on its finding petitioner's FDA-mandated warnings inadequate.

That not only forecloses respondent's claim that this case turned on a quirk of New Hampshire law; it exposes just how dramatically the First Circuit deviated from *Mensing*. *Mensing*'s whole point is that Hatch-Waxman's sameness mandate immunizes a generic product's FDA-mandated warnings from attack because it prohibits generic manufacturers from altering them. 131 S. Ct. at 2577. That *rationale* applies *a fortiori* to claims challenging FDA-mandated generic product design, as the appellate court conceded. App. 10a. The key point here, however, is that the court's decision eviscerates *Mensing*'s *holding*, by allowing precisely what *Mensing* forbids. In short, the jury's $21 million verdict depended on the very thing *Mensing* said it could not.

That cannot be right. And if the stop-selling evasion lets plaintiffs challenge FDA-mandated warnings in defective-design cases, there is no principled reason why plaintiffs could not do so in defective-warnings cases. It would be like *Mensing* never happened; we would be back to the Eighth Circuit's pre-*Mensing* declaration that generic manufacturers are liable because they "were not compelled to market metoclopramide. If they realized their label was insufficient ... they could have simply stopped selling [it]." *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009). The First Circuit might prefer that approach, but *Mensing* bound the court to reject it.

Respondent offers two answers. She first claims petitioner waived this comment k *argument* by withdrawing its comment k *defense*. BIO 14, 19-20, 31-32. Nonsense. As respondent concedes (BIO 14), petitioner repeatedly argued that comment k eliminated any difference between failure-to-warn and design-defect claims for preemption purposes. *E.g.*, Pet'r's Mem. In Supp. Of Summ. J., 2010 WL 1371985, at 31 (Mar. 30, 2010) ("[D]rugs are unavoidably unsafe products, and as such, cannot be defective in design as long as they are accompanied by adequate warnings. As such, any design claim directly implicates warnings and thus, falls under the same preemption analysis.") (citation omitted).

Nothing obligated petitioner to present this legal argument to the jury; the argument's whole point is that comment k *should have prevented this case from reaching the jury* because *Mensing* precludes challenges to generic warnings. It was enough to raise this argument at summary judgment. *City of St. Louis v. Praprotnik*, 485 U.S. 112, 120 (1988). And waiver applies to legal *claims*—not legal *arguments*—anyway. *Yee v. City of Escondido*, 503 U.S. 519, 534-35 (1992).[3]

In any event, the withdrawal of petitioner's comment k defense did not remotely dissuade

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[3] Nor is this a vehicle issue, BIO 20 (claiming review should await a case where "the drug manufacturer has presented a [comment k] defense"). If anything, the withdrawal of this fact-dependent defense makes this an ideal vehicle, because it puts the purely legal question in sharpest relief (like *Mensing*, which was decided at the 12(b)(6) stage).

respondent from mounting the very attacks *Mensing* bars. Indeed, it is astonishing that she now denies challenging the adequacy of petitioner's FDA-mandated warnings at trial (BIO 31). She did so repeatedly:

> Mr. Jensen: [H]ave you assessed whether [petitioner's] label ... has an effective or adequate warning for SJS/TEN?
>
> Dr. Tackett: I do not think it does have an adequate warning or effective warning.

Supp. App. 6a-7a.

> Mr. Jensen: The fact that [FDA later changed the label], what if any bearing does that have on your opinion about the effectiveness or lack thereof of the prior Sulindac label?
>
> Dr. Tackett: Well, it definitely indicates the label was inadequate.

Supp. App. 9a.

> Mr. Jensen: What, if any, opinion have you reached as to whether or not [petitioner's] label had an effective warning for SJS and TEN?
>
> Dr. Tackett: As I've said before, I do not think it was effective. The new label basically has a better warning.

Supp. App. 12a.

Given this record, respondent ultimately asserts this case is *sui generis* because it is hard to convince juries *both* that the warnings are inadequate *and* that the product's risks outweigh its benefits. BIO 12-13 & n.11. Respondent's immodest

suggestion that only her lawyers can whip jurors into a frenzy is baseless. As *Riegel* observed, juries are notoriously ill-equipped to second-guess FDA's expert risk-benefit analysis because they "see[] only the cost of a more dangerous design, and [are] not concerned with its benefits; the patients who reaped those benefits are not represented in court." 552 U.S. at 325.

That is why thousands of plaintiffs continue to pursue generic design-defect claims undaunted by the hurdles respondent alleges. *E.g.*, *In re Darvocet*, 2012 WL 718618 (federal MDL); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479 (E.D.N.Y. 2012) (same); *In re Fosamax*, MDL No. 2243, 2011 WL 5903623 (D.N.J. Nov. 21, 2011) (same). And emboldened by this outlier decision, new claims are being filed weekly.

Ultimately, it is hard to overstate how important it is for this Court to make clear that *Mensing* meant what it said. This verdict was the largest in New Hampshire history, and as the *amici* briefs explain, the First Circuit's demand that generics either withdraw their products or face ruinous liability jeopardizes both the industry and the federal scheme. Br. for Morton Grove 10-11, 16. Indeed, it is hard to conceive a result more at odds with Hatch-Waxman. The statute's whole purpose was to lower healthcare costs by making generic drugs widely available; in *Mensing*'s words, "it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public." 131 S. Ct. at 2582; App. 10a ("There is no doubt that Congress wanted to reduce medical costs by spurring

generic copycat drugs [and *Mensing*] held that Congress cannot have wanted the generic to pay damages under state law for a label that the FDA required.").[4]

Given its frontal assault on Hatch-Waxman's core objectives, the First Circuit rightly acknowledged this case presents "a question of exceptional importance," App. 8a, and asked this Court to provide "a decisive answer." App. 11a. That is the one part of its decision everyone should agree on, and we respectfully submit that this Court should heed its request.

CONCLUSION

This Court should grant the petition and summarily reverse.

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[4] Respondent's claim that petitioner waived its argument regarding Hatch-Waxman's objectives (BIO 21; *id.* 28 n.22) is frivolous. The Petition made this very point, Pet. 31-32, and the Court otherwise can consider any issue "fairly included" in the question presented. Rule 14(1)(a).

November 13, 2012

Respectfully submitted,

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APPENDIX

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

08-CV-358-JL
September 2, 2010; 8:45 A.M.

KAREN L. BARTLETT,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,

TRANSCRIPT OF JURY TRIAL
MORNING SESSION
BEFORE THE HONORABLE JOSEPH N. LAPLANTE

APPEARANCES:

For The Plaintiff:

Keith M. Jensen, Esq., Eric N. Roberson, Esq., Xavier A. Gonzalez, Esq. Bryan Ballew, Esq., Jensen Ballew & Gonzalez, PLLC

For the Defendant:

Joseph P. Thomas, Esq., Paul J. Cosgrove, Ulmer & Berne LLP,

Stephen J. Judge, Esq., Pierre A. Chabot, Esq. Wadleigh, Starr & Peters, PLLC

Court Reporter:

Susan M. Bateman, LCR, CM, CRR, Official Court Reporter, U.S. District Court, 55 Pleasant Street, Concord, NH 03301, (603) 225-1453

* * *

Mrs. Bartlett must prove, first, that Mutual was in the business of selling Sulindac. It is not necessary for Mrs. Bartlett to prove that Mutual sold Sulindac directly to her or directly to the pharmacy that filled her prescription. It is sufficient if Mrs. Bartlett proves that Mutual placed Sulindac into the stream of commerce.

A defect in design occurs when the product has been manufactured in conformity with the manufacturer's design but the design itself presents unreasonable danger to consumers.

In deciding whether Sulindac's design presented unreasonable danger, you should consider the usefulness and desirability of the product to the public as a whole. A product is defective as designed if the magnitude of the danger outweighs the utility or usefulness of the product.

You should also consider whether Sulindac's risk of danger, if any, could have been reduced without significant impact on the product's effectiveness or its manufacturing cost. Liability may exist if the manufacturer did not take available and reasonable steps to lessen or eliminate the danger of even a useful and desirable product.

Bear in mind that a manufacturer is not obliged to design the safest possible product, or a safer product, or one as safe as others make, so long as the design it has adopted is not unreasonably dangerous.

By the same token, you may find that a product's design was unreasonably dangerous even if the plaintiff has not presented evidence of an alternative design that could have made the product safer.

Now, if you determine that Sulindac was unreasonably dangerous, you may consider the presence and efficacy or effectiveness of a warning to avoid an unreasonable risk of danger from foreseeable uses of the product. The plaintiff must prove that the product was unreasonably dangerous even with its warning.

If you determine that Sulindac was unreasonably dangerous and that a warning was not present and effective to avoid that unreasonable danger, then you must find Mrs. Bartlett has proven this element of her claim, a defect in design. However, if you determine that Sulindac was unreasonably dangerous, but that a warning was present and effective to avoid that unreasonable danger, then you must find for Mutual.

A manufacturer is not responsible for injuries caused by a product's defective condition unless the purpose and manner of the plaintiff's use of the product were reasonably foreseeable by the manufacturer. In terms of foreseeability, we are talking about reasonable foreseeability and not some sort of prophetic vision as to what might conceivably happen. A manufacturer may be held liable even if the user employs the product in an unintended but foreseeable manner.

A product's defective condition is a legal cause of the plaintiff's injuries if it directly and in natural and continuous sequence produces or substantially contributes to producing the injuries, so that it can reasonably be said that but for the defective condition the injuries would not have occurred.

In determining whether the defective condition was a legal cause of the plaintiff's injuries, you need

not find that the defective condition was the sole cause of the injuries, but only that it was a substantial factor in bringing about the injuries, even though other factors may have contributed to the cause of the injuries.

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

08-CV-358-JL
August 20, 2010; 1:00 P.M.

KAREN L. BARTLETT,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,

DAY 5
TRANSCRIPT OF TRIAL
AFTERNOON SESSION
BEFORE THE HONORABLE JOSEPH N. LAPLANTE
AND A JURY

APPEARANCES:

For The Plaintiff:

Keith M. Jensen, Esq., Eric N. Roberson, Esq., Xavier A. Gonzalez, Esq. Bryan Ballew, Esq., Jensen Ballew & Gonzalez, PLLC

For the Defendant:

Joseph P. Thomas, Esq., Paul J. Cosgrove, Ulmer & Berne LLP,

Stephen J. Judge, Esq., Pierre A. Chabot, Esq. Wadleigh, Starr & Peters, PLLC

Court Reporter:

Sandra L. Bailey, LCR, CM, CRR, Official Court Reporter, U.S. District Court, 55 Pleasant Street, Concord, NH 03301, (603) 225-1454

* * *

MR. JENSEN: Exhibit 48B, Sulindac label. Permission to publish.

THE COURT: The Sulindac label? So it's a full exhibit?

MR. JENSEN: I gather.

THE COURT: Okay. Of course you can publish it.

Q. By MR. JENSEN: Where is—strike that. Is—

THE COURT: It's a full exhibit?

THE CLERK: Yes, your Honor.

THE COURT: The identification is not stricken from that but, okay, proceed.

Q. Is SJS and TEN mentioned in the Sulindac label?

A. It is.

Q. Approximately what paragraph do we need to read to before we can see it?

A. It's pretty far down there. If you were to number them, it's probably around paragraph 64.

Q. Okay. And is this label the one, the one that was, it says revised February 2002. Do you see that, sir?

A. Yes, I do.

Q. And was this or was this not the label that was in effect in December of 2004 when Karen Bartlett was prescribed this drug?

A. It would be the label that would be in effect.

Q. Okay. And have you assessed whether or not this label to start with has an effective or adequate warning from SJS/TEN?

A. I do not think it does have an adequate warning or effective warning.

Q. Have you assessed this warning section in here and whether or not that related to your opinion?

A. Yes.

Q. Okay. And before I get to that, have you also evaluated any new label for Sulindac beyond this one what we're looking at?

A. Yes.

* * *

* * *

Q. Strike that. This says two things here. It says, quote, stop your NSAID and call your healthcare provider. Is that correct?

A. That's correct.

Q. How does that relate to the fact that it's putting information in a patient's hands that they don't even talk to their doctor first. They are telling them you have to stop the medication and to call their doctor. What relevance, if any, is that to your opinion?

A. If you keep taking the medication, for example, if you call your doctor but continued taking the medication because you had a prescription for it, you're adding more drug there which can make the condition get actually worse. They're saying stop the medication, call your doctor so there's no more exposure.

Q. And does this medication guide for Sulindac also list a number of other NSAIDS on the market?

A. It does.

Q. Approximately—you don't have to count—how many.

A. There's probably 10 to 14 I think there, I believe.

Q. Okay. And you mentioned that there is an order to create this new label. Is that correct, sir?

A. Correct.

Q. Who did that order come from?

A. The Food and Drug Administration.

Q. What if any bearing—did this order come from just Sulindac or for other NSAIDS as well?

A. It was for all nonsteroidal anti-inflammatory drugs.

Q. The fact it was for all NSAIDS, what if any bearing does that have on your opinion about the effectiveness or lack thereof of the prior Sulindac label?

A. Well, it definitely indicates the label was inadequate.

Q. As well as for the other NSAIDS?

A. Yes.

Q. Let's address the warning section of the prior label, sir, and I direct you to a section called hypersensitivity. Tell us what it's talking about generally, first of all, before we go into specifics.

A. This is basically talking about hypersensitivity reaction which when you talk about hypersensitivity it's just a, seems to be an excessive response, but in my reading of this label it basically describes hypersensitivity that primarily describes liver dysfunction.

Q. And why do you say that, that it primarily describes liver dysfunction?

A. Well, it starts off again, and remember, you want the more serious things at the front, and so if you just look under hypersensitivity it starts off including abnormalities in one or more liver function tests. These are laboratory tests that assess whether your liver is undergoing damage. And then it mentions severe skin reactions that occurred during therapy. And it also talks about unexplained fever, rash, constitutional symptoms which could be other organ effects, and it also has elevated temperature.

Again, it talks about abnormalities in liver function. And so this primarily talks about liver dysfunction that is caused by the drug.

* * *

* * *

THE COURT: Take a different tack at it. If he still objects, we will approach.

MR. THOMAS: Oh, I'm sorry, but it is the substance, it is an undisclosed substance.

THE COURT: Okay. That's the grounds?

MR. THOMAS: Yes.

THE COURT: Okay. That's the grounds?

MR. THOMAS: Yes.

THE COURT: Understood. Proceed.

Q. BY MR. JENSEN: How does this statement about hypersensitivity in relation to liver relate to the efficacy or the adequacy of a label?

THE COURT: No. No. We will cover that at the—we will cover that at the break.

Q. Okay. Have you reached a conclusion as to whether the SJS and TEN warning in the warning section of the new label is better than the fact that there is no SJS and TEN warning in the old label.

A. Yes.

Q. What is it?

A. It is better.

Q. Have you reached a conclusion as to whether the new label is better by having a medication guide in it?

A. Absolutely, yes.

Q. Have you reached—

THE COURT: You've really got to stop leading. You've got to ask open-ended questions.

Q. What, if any, opinion have you reached as to whether or not the old label had an effective warning for SJS and TEN?

A. As I've said before, I do not think it was effective. The new label basically has a better warning. It's clearer and the presence of a medication guide makes it even better with regard to giving information to the patient as well as to the doctor that may be reading the label.

THE COURT: All right, you want to get into that area. You were trying to approach, so it's probably a good time for a break so we don't waste the jury's time while we argue about that. Let's take the afternoon break.

AMICUS CURIAE BRIEF

SUPREME COURT, U.S.
FILED
AUG 31 2012

No. 12-142

IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,

Petitioner,

v.

KAREN L. BARTLETT,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

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BRIEF OF THE GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the First Circuit erred when it created a circuit split and held—in clear conflict with this Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), *reh'g denied*, 132 S. Ct. 55 (2011); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)—that federal law does not preempt state law design-defect claims targeting generic pharmaceutical products because the conceded conflict between such claims and the federal laws governing generic pharmaceutical design allegedly can be avoided if the makers of generic pharmaceuticals simply stop making their products.

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IN THE

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BRIEF OF THE GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF *AMICUS CURIAE* AND SUMMARY OF ARGUMENT

The Generic Pharmaceutical Association ("GPhA") is a voluntary, non-profit association[1] comprised of

[1] Pursuant to Supreme Court Rule 37.2(a), all parties were informed ten days in advance of the filing of this brief, and have consented to its filing. Correspondence demonstrating advance notice to the parties and their consent to this filing

more than 70 manufacturers and distributors involved in the generic pharmaceutical industry. GPhA's members provide American consumers with generic medications that are as safe and effective as their brand-name counterparts, but at a fraction of the cost. "All generic drugs approved by [the Food and Drug Administration ("FDA")] have the same high quality, strength, purity and stability as brand-name drugs."[2] Generic drugs today account for nearly 80% of prescriptions dispensed in the United States, but just 27% of prescription spending.[3] Generic pharmaceutical products are used to fill more than 3.2 billion prescriptions each year, saving the American consumer $193 billion in 2011 and

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have been filed with the Clerk. Pursuant to Supreme Court Rule 37, *amicus* states that no counsel for a party authored any part of this brief and that no person or entity other than *amicus*, its members, and its counsel have made any monetary contribution intended to fund the preparation or submission of this brief.

[2] Generic Drugs: Questions and Answers, U.S. Food and Drug Administration, *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/default.htm (accessed August 24, 2012).

[3] IMS Institute for Health Care Informatics, *The Use of Medicines in the United States: Review of 2011*, at 26 (Apr. 2012) ("Use of Medicines 2011"); Generic Pharmaceutical Association, Generic Drug Savings in the U.S. (4th ed. 2012), *available at* http://www.gphaonline.org/sites/default/files/IMS%20Study%20Aug%202012%20WEB.pdf (accessed August 26, 2012) ("Generic Drug Savings 2012").

more than $1 trillion over the last 10 years. *Id.* GPhA's members are committed to providing safe, lower-cost medications to all Americans, including the poor and the elderly.

The case before the Court affects the interests of GPhA's members in that it re-opens avenues of liability that this Court decisively closed in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) *reh'g denied*, 132 S. Ct. 55 (2011). In *Mensing*, the Court made very clear that generic pharmaceutical manufacturers are required under federal law to produce products that are the "same as" their brand-name counterparts. *Id.* at 2474–75. State tort law requirements that conflict in any way with the federal duty of "sameness" are preempted. *Id.* at 2570–71, 2474–75.

Bartlett v. Mutual Pharmaceutical Co., 678 F.3d 30 (1st Cir. 2012) *petition for cert. filed* July 31, 2012 (No. 12-142), is logically and legally indistinguishable from *Mensing*. In both cases, the respective plaintiffs sought to impose a state law duty that ran afoul of the federal duty of sameness – that is, generic drugs must have the same design and label as their respective brand-name counterparts. *See* 21 U.S.C. § 355(j)(2)(A)(ii), (v). And in both cases, the plaintiffs argued that the generic manufacturers could have complied with both state and federal law by simply withdrawing their drugs from the market.

In *Mensing*, this Court found preemption. In *Bartlett*, however, the First Circuit did not find

preemption, reasoning that conflicts "might" be avoided if Petitioner decided not to manufacture generic drugs at all. *Bartlett*, 678 F.3d. at 37.

The proposition that conflict preemption is inapplicable because a generic manufacturer can remove its drug from the market was rejected by this Court in *Mensing* and every other Circuit Court to have considered it since. Quite simply, if the possibility of withdrawing a drug from the market was sufficient to satisfy the Supremacy Clause, then *Mensing* would have come out the other way. Moreover, the First Circuit's approach would render conflict preemption meaningless, because state and federal regulatory and tort law can (almost) always be satisfied by leaving the regulated business.

Perhaps more troubling is that *Bartlett* directly undermines the expressly stated purposes of Congress in enacting the Hatch-Waxman Amendments: to promote the availability of lower-cost generic drugs. *See generally* 21 U.S.C. § 355(j). In order to curb rising costs of prescription medication, Congress streamlined the market entry process for generic drugs and established the federal duty of sameness – applicable to both design and warnings.

The results have been nothing short of astonishing. While it typically costs more than one billion dollars to bring a brand product to market, the research and development costs for a generic

drug are only 1 to 2 million.[4] These savings are then passed on to all consumers, not the least of which is the federal government. And the bottom line for Congress and American taxpayers is that generic drugs have saved the American healthcare system more than $1 trillion over the last 10 years.[5] When the Hatch-Waxman Amendments were passed, their proponents estimated that they would save American consumers $920 million over the following *twelve years*.[6] These savings are now achieved every *two days*.

The driving force behind these benefits is the availability of low-cost generic drugs made possible by the Hatch-Waxman Amendments. *Bartlett* threatens to upend this statutory purpose by forcing generic drugs out of the market altogether. The First Circuit upheld the imposition of state tort liability – to the tune of $21.06 million, 678 F.3d at 43 – based on nothing more than Petitioner's decision to distribute a generic drug that carries inherent, but recognized risks – risks that were well known by the FDA, understood by the medical community decades before Respondent's injuries occurred, and disclosed in the FDA-approved

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[4] *See* U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Office of Science and Data Policy, ASPE Issue Brief, Expanding Use of Generic Drugs at 4–5 (2010), *available at* http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.shtml.

[5] Generic Drug Savings 2012.

[6] *See* H.R. Rep. No. 98-857(I) (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2649.

labeling. *Id.* at 44 (noting that sulindac has a "miniscule" but "recognized" risk of Stevens-Johnson Syndrome ("SJS") and toxic epidermal necrolysis ("TEN")).

This Court acknowledged the "unfortunate hand that federal drug regulation has dealt" those who suffer rare-but-warned-about side effects from generic drugs. *Mensing*, 131 S. Ct. at 2581. Nevertheless, the Court stressed that the Supremacy Clause may not be distorted "in order to create similar pre-emption across a dissimilar statutory scheme." *Id.* at 2582. The converse is also true; the Supremacy Clause should not be distorted to create dissimilar preemption across a similar statutory scheme.

Yet this is exactly what the lower court did in *Bartlett*. The First Circuit, faced with the same regulatory scheme at issue in *Mensing*, fabricated a crude remedy for injuries sustained while using generic drugs. Along the way, it ignored the rationale of *Mensing* and ran roughshod over the statutory scheme carefully crafted by Congress.

The Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. § 301 *et seq.*, and the Hatch-Waxman Amendments involve a delicate balance of private and public interests, which is precisely why it is left to "Congress and the FDA . . . to change the law and regulations if they so desire." *Id.* Courts may not ignore controlling law, nor may they concoct remedies that frustrate Congress' clearly stated legislative goals.

As the *Bartlett* Court's decision ignores these bedrock principles, GPhA respectfully requests that this Court grant Petitioner's petition for writ of certiorari and accept the First Circuit's invitation to provide "a decisive answer from the only court that can supply it." 678 F.3d at 38.

REASONS FOR GRANTING THE PETITION

A. THE DECISION OF THE FIRST CIRCUIT IS WHOLLY INCONSISTENT WITH THE HOLDING IN *MENSING*

Last year in *Mensing*, this Court embraced three propositions that control this case:

1. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it";
2. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes"; and
3. The Court will not "permit an approach to pre-emption that renders conflict pre-emption all but meaningless" by rendering "most conflicts between state and federal law illusory."

131 S. Ct. at 2579–81.

Here, Respondent purports to proceed on a design defect theory. A traditional design defect claim is

based on a manufacturer's duty to change the design of a product to render it safer. But, as recognized by the overwhelming majority of courts to consider the question, such a duty would fail for the same reason that the claims failed in *Mensing*; the federal duty of "sameness" applies equally to both warnings and design.[7] The First Circuit agrees. *See Bartlett*, 678

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[7] *See, e.g., In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012) (holding that the duty of "sameness" also preempts design defect claims); *In re Accutane Prods. Liab.*, MDL No. 1626, 2012 WL 3194952, at *2–3 (M.D. Fla. Aug. 7, 2012) (dismissing design defect claim based on the federal duty of "sameness"); *Aucoin v. Amneal Pharms., LLC*, Civ. A. No. 11-1275, 2012 WL 2990697, at *9 (E.D. La. July 20, 2012) (same); *Lashley v. Pfizer, Inc.*, --- F.Supp.2d ----, Civ. A. No. 1:09CV749HSO-JMR, 2012 WL 2459148, at *11 (S.D. Miss. June 27, 2012) ("Because [the generic manufacturer] could not have altered their package inserts without FDA approval, Plaintiffs' claim based upon defective design is preempted by federal law."); *Johnson v. Teva Pharms. USA, Inc.*, No. 2:10 CV 404, 2012 WL 1866839, at *4 (W.D. La. May 21, 2012) (dismissing design defect claim under *Mensing*); *Eckhardt v. Qualitest Pharms. Inc.*, --- F. Supp. 2d ----, Civ. A. No. M-11-235, 2012 WL 1511817, at *6–7 (S.D. Tex. Apr. 30, 2012) (holding that design defect claim is preempted, because "Generics were required to produce a drug that was equivalent to the brand-name drug"); *Metz v. Wyeth LLC*, Civ. A. No. 8:10-CV-2658-T-27AEP, 2012 WL 1058870, at *4 (M.D. Fla. Mar. 28, 2012) ("A claim that Actavis should have redesigned metoclopramide to alleviate the risks associated with its long-term use would be preempted under *Mensing*."); *Lyman v. Pfizer, Inc.*, No. 2:09-CV-262, 2012 WL 368675, at *4 (D. Vt. Feb. 3, 2012) (holding that design-defect claims "are preempted as well by *Mensing*'s logic"); *In re: Fosamax (Alendronate Sodium) Prods. Liab. Litig (No. II).*, MDL No. 2243,, 2011 WL 5903623, at *6 (D.N.J. Nov. 21, 2011) (holding that design defect claims are preempted, "because FDA requires generic Fosamax to have the same active ingredient as Fosamax"); *and*

F.3d at 37 ("Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)").

But rather than accept this reality, the *Bartlett* Court recognized a state law duty for manufacturers of generic drugs to withdraw their FDA-approved drugs from the market. *Id.* at 38 ("[W]hile the generic maker has no choice as to label—the decision to make the drug and market it in New Hampshire is wholly its own."). This claim, of course, has absolutely nothing to do with the design of sulindac – a "one-molecule drug" with inherent risks and no possible alternative design. *Id.* at 37.

In any event, the option of withdrawing a product from the market does not represent an end around *Mensing*. As a preliminary matter, the same argument could have been – and, indeed, was – made in *Mensing*, and this Court found that the plaintiffs' state law claims were preempted anyway.

What is more, if the ability to withdraw a product from the market were sufficient to defeat impossibility preemption, "it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force." *Mensing*, 131 S. Ct. at 2579. *Mensing* bars "an approach to pre-emption that renders conflict pre-emption all but

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Stevens v. PLIVA, Inc., Civ. A. No. 6:10-0886, 2011 WL 6224569, at *2 (W.D. La. Nov. 15, 2011) (holding that "federal law pre-empts state laws imposing the duty to change a drug's design").

meaningless." *Id.* So yet again, the possibility that the manufacturer of a generic drug could have chosen to stop doing business is constitutionally irrelevant.

In sum, as a generic manufacturer, Petitioner has no more freedom to change the design of its drug than it does to change the warnings. The First Circuit was fully aware of these facts, but strained to avoid preemption with the unremarkable observation that Petitioner was never obligated to market its drug in the first place. This approach ignores the teachings of *Mensing* and renders conflict preemption largely meaningless. But because *Bartlett* involved the same regulations and same arguments as *Mensing*, the First Circuit was not at liberty to reach a different result. GPhA urges this Court to correct the decision below.

B. THE DECISION BELOW CONFLICTS WITH THE *MENSING* ANALYSES OF OTHER CIRCUITS

The First Circuit below embraced a failure-to-withdraw theory under the guise of a design defect claim, but acknowledged "tension" with *Mensing*'s "rationale." *Bartlett*, 678 F.3d at 38. Describing *Mensing* as setting forth a "policy of encouraging generics by preempting state tort claims," *id.* at 37, the *Bartlett* Court challenged this Court to provide a "decisive answer" to the viability of Respondent's so-called design defect claim. *Id.*

But this Court has already done so. For that reason, the First Circuit's decision stands as an outlier from at least two of its sister circuits (which considered and rejected this argument after plaintiffs raised it in post-*Mensing* briefs)[8] and

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[8] *See, e.g., Strayhorn v. Wyeth Pharms., Inc.*, Nos. 11-2058-STA-CGC, et al., 2012 WL 3261377, at *16 (W.D. Tenn. Aug. 8, 2012) ("[A]ll of Plaintiffs' assorted claims raising allegations that the Generic Defendants failed to remove metoclopramide from the market are invalid due to *Mensing* and *Smith*'s rejection of this theory."); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, Nos. 2:11-MD-2226-DCR, et al., 2012 WL 2457825, at *1 (E.D. Ky. June 22, 2012) (observing that the plaintiffs' failure-to-withdraw claims "failed to persuade either the Supreme Court or the Eighth Circuit on remand in *Mensing*, and the Sixth Circuit in *Smith*"); *Johnson*, 2012 WL 1866839, at *5 (rejecting "failure-to-withdraw" argument based on Supreme Court and Eighth Circuit's rejection of the precise argument); *Fulgenzi v. PLIVA, Inc.*, Case No. 5:09CV1767, 2012 WL 1110009, at * 7 n.5 (N.D. Ohio Mar. 31, 2012) (noting that the failure-to-withdraw argument was "overruled" by the Supreme Court in *Mensing*); *Bowman v. Wyeth, LLC*, Civ. No. 10-1946 JNE/SER, 2012 WL 684116, at *6 (D. Minn. Mar. 2, 2012) (dismissing failure-to-withdraw claim, because it was already rejected by both the Supreme Court and the Eighth Circuit); *Moretti v. PLIVA, Inc.*, No. 2:08-CV-00396-JCM, 2012 WL 628502, at *5–6 (D. Nev. Feb. 27, 2012) (dismissing failure-to-withdraw theory based on, *inter alia*, the Sixth and Eighth Circuits' rejection of this very theory); *Moretti v. Mut. Pharm. Co.*, Civ. No. 10-896, 2012 WL 465867, at *5 (D. Minn. Feb. 13, 2012) (rejecting proposition that a generic defendant can circumvent *Mensing* preemption by simply withdrawing from the market, because this argument was rejected by the Eighth Circuit on remand); *Lyman*, 2012 WL 368675, at *4 n.5 (recognizing that the Eighth Circuit rejected the failure-to-withdraw theory upon remand in *Mensing*); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 658–59 (D. Md. 2011) (noting that the proposition that the ability to

dozens of federal district courts that have addressed the issues.

In fact, before *Mensing* reached the Supreme Court, the Eighth Circuit had accepted the plaintiff's argument that a generic manufacturer could satisfy state and federal law by withdrawing the drug from the market. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009), *rev'd*, 131 S. Ct. 2567 (2011). In reversing the Eighth Circuit, this Court rejected this reasoning and refused to rehear the case based on the plaintiffs' suggestion that the Court had "overlook[ed] the fact that the [generic manufacturers] could have 'independently' complied with both state and federal law simply by suspending sales of generic metoclopramide with warnings that they knew or should have known where inadequate." Respondents' Petition for Rehearing, *PLIVA, Inc. v. Mensing*, Nos. 09-993, 09-1039, 09-1501, 2011 WL 2874547, at *1 (July 18, 2011).

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withdraw a product serves as an end around *Mensing* was rejected by the Supreme Court, Eight Circuit, and Sixth Circuit); *Fullington v. PLIVA, Inc.*, No. 4:10CV00236 JLH, 2011 WL 6153608, at *6 (E.D. Ark. Dec. 12, 2011) *reconsideration denied*, 2012 WL 2918711 (E.D. Ark. July 17, 2012) (noting that plaintiff's suggestion that preemption could be avoided by removing the drug from the market had been "overruled" by the Supreme Court and the Eighth Circuit on remand in *Mensing*); *and In re Fosamax (Alendronate Sodium) Products Liab. Litig.*, 2011 WL 5903623, at *6 n.5 (recognizing that the plaintiffs' arguments regarding an alleged failure to withdraw are "essentially a re-argument of *Mensing*," such that dismissal of these claims is necessitated by "binding law").

On remand, the Eighth Circuit vacated the portion of its earlier opinion that embraced the failure-to-withdraw theory and denied the plaintiff's motion to file a supplemental brief on that issue. *See Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011). In doing so, the Eighth Circuit understood that this Court had settled the question of whether the ability to withdraw a drug from the market allows a plaintiff to avoid preemption.

The Sixth Circuit also rejected this "failure-to-withdraw" argument. *See Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) *cert. denied*, 132 S. Ct. 2103 (2012). The district court in *Smith* granted the generic manufacturers' motion for summary judgment on preemption grounds. On appeal, the plaintiffs suggested a "failure to suspend sales" theory would be "wholly consistent with *Mensing*," because "no federal statute or regulation prohibited [generic manufacturers] from 'independently' suspending sales of their product out of concern that their labeling lacked adequate warnings." Appellants' Supplemental Letter Brief, *Smith v. Wyeth, Inc.*, Nos. 09-5460, 5461, 5509, 2011 WL 3662688, at *6 (Aug. 15, 2011). The Sixth Circuit was not persuaded, and affirmed summary judgment. *Smith*, 657 F.3d at 423.

Thus, the First Circuit – without even addressing the merits of the Sixth and Eighth Circuit's positions, not to mention the fact that the failure-to-withdraw argument *twice* failed to persuade this Court – has created a circuit split. GPhA respectfully requests that the Court grant Mutual's

petition for certiorari and bring the First Circuit into line with the well-reasoned decisions from nearly every other court to have addressed the issue.[9]

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[9] *See Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1352 n.14 (N.D. Ga. 2012) ("[A]ny such state law duty [to stop selling a generic drug] would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce."); *Jacobsen v. Wyeth, LLC*, Civ. A. No. 10-0823, 2012 WL 3575293, at *11 (E.D. La. Aug. 20, 2012) ("To require a generic manufacturer to remove a drug from the market would repudiate the label approved by the FDA."); *Aucoin*, 2012 WL 2990697, at *9 (rejecting the viability of a failure-to-withdraw theory, because "[t]o require a generic manufacturer to remove a drug from the market would repudiate the label approved by the FDA"); *Brinkley v. Pfizer, Inc.*, No. 10-0274-CV-W-SOW, 2012 WL 1865402, at *3–5 (W.D. Mo. May 22, 2012) (dismissing claims for, *inter alia*, failure to stop selling metoclopramide, because "the Court fails to see how these allegations differ from those in *Mensing*"); *Eckhardt*, 2012 WL 1511817, at *6–7 ("[A] state law requirement that the drug be completely withdrawn from the market, based solely on a theory that the federally mandated label was inadequate, would also impermissibly conflict with federal law and be preempted."); *Metz*, 2012 WL 1058870, at *4 ("To the extent Plaintiffs contend that Actavis should have pulled the generic version of metoclopramide from the market, such claim is also preempted."); *Cooper v. Wyeth, Inc.*, Civ. A. No. 09-929-JJB, 2012 WL 733846, at *6 (M.D. La. Mar. 6, 2012) ("If state law could *require* a generic drug manufacturer to wholly withdraw from the market based on the unreasonable danger of the product (which is all a successful failure to withdraw from the market claim could be), it *necessarily* must repudiate the label approved by the FDA. But that is precisely what *Mensing* teaches state law cannot do.") (emphasis in original); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL No. 2226, 2012 WL 718618, at *2–4 (E.D. Ky. Mar. 5, 2012)

C. THE DECISION BELOW WOULD UNDERMINE THE PURPOSE OF THE HATCH-WAXMAN AMENDMENTS

If allowed to stand, the First Circuit's opinion would erode the foundation of the pharmaceutical industry by allowing lay juries to second guess the FDA – the expert agency entrusted by Congress to determine which drugs should be on the market. Manufacturers of generic drugs would be forced to withdraw from the market or be subjected to the whims of 50 states' tort regimes simply for marketing a product with the FDA's approval.

(rejecting the viability of a failure-to-withdraw claim, because "the idea that [generic manufacturers] should have simply stopped selling propoxyphene is an oversimplified solution that could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether"); *Coney v. Mylan Pharms., Inc.*, No. 6:11-CV-35, 2012 WL 170143, at *5–6 (S.D. Ga. Jan. 19, 2012) (dismissing a failure-to-withdraw claim, because "[f]inding that state law prohibits Mylan from doing what federal law explicitly requires Mylan to do would be tantamount to conferring supremacy upon the state law"); *Gross*, 825 F. Supp. 2d at 659 (holding that a state law duty to withdraw an FDA-approved product is preempted, because it "would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce"); *and In re Reglan Litig.*, No. 289, 2012 WL 1613329 (N.J. Sup. Ct. May 4, 2012) (rejecting argument that generic manufacturers could independently meet both state and federal law by withdrawing the product from the market and noting that the "conflict between state and federal law would be much more pronounced if the state courts upheld a decision that an FDA-approved drug should not have been on the market").

In passing the Hatch-Waxman Amendments, Congress left nothing to the imagination as to the statute's goal:

> The purpose of [the Hatch-Waxman Amendments] is to make available more low cost generic drugs by establishing a generic drug approval procedure . . . .

H.R. Rep. No. 98–857, pt. 1, at 14 (1984).

As to the ends and means of the Hatch-Waxman Amendments, this Court spoke unanimously in *Mensing*:

> As the majority explains, to accomplish this goal the [Hatch-Waxman Amendments] establish an abbreviated application process for generic drugs. The abbreviated approval process implements the amendments' core principle that generic and brand-name drugs must be the "same" in nearly all respects . . . . By eliminating the need for generic manufacturers to prove their drugs' safety and efficacy independently, the Hatch-Waxman Amendments allow generic manufacturers to bring drugs to market much less expensively.

Mensing, 131 S. Ct. at 2583 (Sotomayor, J., dissenting) (citations omitted).

The federal duty of sameness allowed Congress to eliminate the need for generic manufacturers to repeat "costly and lengthy clinical testing," *id.* at

2574, thereby removing unnecessary hurdles to market entry.

Congress' efforts to promote the availability of generic drugs have borne fruit. Today, nearly 80% of all prescriptions are filled with generic products, but they account for only 27% of prescription drug costs.[10] The Congressional Budget Office ("CBO") estimated that the availability of generic drugs saved between $8 billion and $10 billion in 1994.[11] By 2011, these savings increased to $193 billion annually – more than $1 billion every two days – with total savings exceeding one trillion dollars over the last ten years.[12]

These data illustrate with clarity that the Hatch-Waxman Amendments have benefited consumers by making it faster and cheaper for manufacturers of generic drugs to enter the market. The savings are the direct result of lower costs of market entry and, by extension, the availability of generic drugs as low-cost alternatives to brand-name products. While costs typically exceed one billion dollars to bring a name-brand drug to market, the research and development costs for a generic drug under the ANDA process are only one-to-two million.[13] By

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[10] *See* Generic Drug Savings 2012; Use of Medicines 2011.

[11] CBO Report, "How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" at 5 (July 1998) ("Generics and Drugs 1998").

[12] Generic Drug Savings 2012.

[13] *See* U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Office of

streamlining market access, the Hatch-Waxman Amendments foster competition, thereby driving down prices, because generic counterparts to almost all branded drugs are now available. As noted by the CBO, "Before the [Hatch-Waxman Amendments], only 35 percent of the top-selling drugs no longer under patent had generic copies available. Today, nearly all do."[14]

In the specific case of sulindac, the regulatory scheme created by Hatch-Waxman has worked exactly as Congress intended: Eight generic preparations of sulindac are currently approved by the FDA.[15]

The First Circuit's decision in *Bartlett* threatens to roll back the achievements of the Hatch-Waxman Amendments by creating an unacceptable risk that manufacturers such as Petitioner will pull their products from the market rather than face state liability simply for selling an FDA-approved drug. Whereas "the purpose of . . . the [Hatch-Waxman Amendments] is to make available more low cost generic drugs," the First Circuit's ruling would drive

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Science and Data Policy, ASPE Issue Brief, Expanding Use of Generic Drugs at 4–5 (2010), *available at* http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.shtml.

[14] Generic and Pricing 1998, at 37.

[15] *See* U.S. Food and Drug Administration, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, *available at* www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm (accessed August 24, 2012).

generics from the market – essentially winding back the clocks to 1983, when skyrocketing healthcare costs prompted Congress to take action in the first place.

In sum, if this Court were to allow the First Circuit's decision to stand, the "special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public," *Mensing*, 131 S. Ct. at 2582, would be completely gutted. Congress' goal of "get[ing] generic drugs into the hands of patients at reasonable prices – fast" would be directly undermined. *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001).

But a when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), the state law is "without effect." *M'Culloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819). A state-law duty is not cognizable if it frustrates the purpose of federal law, regardless of "whether that 'obstacle' goes by the name of 'conflicting; contrary to; . . . repugnance; difference; irreconcilability; inconsistency; violation; curtailment; . . . interference,' or the like." *Geier v. Am. Honda Co.*, 529 U.S. 861, 873 (2000) quoting *Hines*, 312 U.S. at 67 (alterations in original).

Significantly, "pre-emption cases ordinarily *assume* compliance with the state-law duty in question." *Id.* at 882 (emphasis in original). The question, therefore, is whether compliance with a

state law duty to remove generic drugs from the market would conflict with Hatch-Waxman's purpose "to make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 4.

The conflict between state law and federal objectives in *Bartlett* is even more pronounced than in *Geier*. Unlike *Geier*, which involved an agency *regulation*, Respondent's failure-to-withdraw claim strikes at the heart of a landmark federal *statute*. In passing the Hatch-Waxman Amendments, Congress' express purpose was to ensure that generic drugs are on the market to increase competition and decrease costs. Thus, a state tort duty to pull those drugs from the market – or face state tort liability if you don't – stands as an obstacle to the purposes and objective of the Hatch–Waxman Amendments.

The First Circuit's logic ignores this basic analysis. By sleight of hand it avoids "impossibility" preemption – but only by palming – and shredding – the card of Congressional intent. Accordingly, beyond the fact that *Bartlett* contravenes *Mensing*'s controlling holding, *see, generally* Cert. Pet. and *supra* Sections A–B, Respondent's failure-to-withdraw claim would frustrate the purposes and objectives of the Hatch-Waxman Amendments and, therefore, must fail.

D. THE DECISION TO PROVIDE A REMEDY TO THOSE WHO EXPERIENCE A KNOWN SIDE EFFECT OF A GENERIC DRUG MUST BE MADE BY CONGRESS, NOT THE COURTS, DUE TO THE DELICATE BALANCE OF PUBLIC AND PRIVATE INTERESTS INVOLVED

Bartlett simply cannot be reconciled with *Mensing*, and it clearly is inimical to the purposes of the Hatch-Waxman Amendments. Further, the First Circuit recognized that Respondent's injuries (SJS/TEN) were the product of a hypersensitivity reaction, a "miniscule" but "recognized" risk inherent with the drug. *Bartlett*, 678 F.3d at 44. It also acknowledged that the labeling for sulindac identified SJS/TEN as a potential adverse reaction.[16]

With full access to post-marketing surveillance data, scientific literature, and three decades of regulatory experience with sulindac, the FDA has approved, and continues to approve, the

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[16] Indeed, the risk of SJS from sulindac has been known for more than 30 years, long before Congress adopted the Hatch-Waxman Amendments. *See* Husain Z, Runge LA Jabbs JM, Hyla JA, *Sulindac-induced Stevens-Johnson syndrome: Report of 3 Cases*, J. Rheumatol (1981 Jan–Feb; 8(1):176–79); Glen D. Park et al., *Serious adverse reactions associated with sulindac*, 142 Arch. Internal Med. 1292–94 (1982). SJS and TEN are known risks other nonsteroidal anti-inflammatory drugs as well. Notwithstanding the known risks, these drugs are prescribed millions of times each year for their analgesic, fever-reducing, and anti-inflammatory properties.

manufacture and marketing of the drug. Thirty years of experience has not altered the FDA's view that sulindac is safe and effective when used in accordance with its FDA-approved labeling. *But see Bartlett*, 678 F.3d at 38 (allowing "second-guessing [of] the FDA" by lay juries).

Sulindac is one of many tools available for physicians, who evaluate the risks and benefits of a drug based on the unique circumstances of each patient. That sulindac, along with all prescription products, has inherent risks does not make its design defective: "Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." Restatement (Second) of Torts § 402A, cmt. k (1965).

However understandable, the First Circuit's desire to provide a remedy for Respondent's injury has no legal basis. In adopting such a construct, the First Circuit ignored Congress' clearly stated goals and abdicated its duty to follow controlling law.

In *Mensing*, this Court acknowledged the "unfortunate hand" dealt by federal drug regulations, *Mensing*, 131 S. Ct. 2581, but it also recognized that these same regulations were adopted to promote the expansion of the generic market and, by extension, lower the cost of prescription drugs. *Id.* at 2582. Because "different federal statutes and regulations may, as here, lead to different pre-emption results," this Court declined to second-guess Congress and "distort the

Supremacy Clause in order to create similar
emption across a dissimilar statutory scheme."

In passing the Hatch-Waxman Amendm
Congress struck a careful balance between p
and private interests. As this litig
demonstrates, state tort law upsets this balanc
jury focuses on a particular plaintiff's injury, n
the overall benefits of a drug; "[t]he patients
reaped those benefits are not represented in cc
Riegel v. Medtronic, Inc., 128 S. Ct. 999,
(2008). For that reason (among others), it simp
not for the *Bartlett* Court, or any court for
matter, to second-guess Congress and recogn
state tort remedy that conflicts with federal law

If and when Congress writes a different la
will become subject to the Supremacy Clause,
must be followed by the courts. But in the cu
case, the *Bartlett* Court failed to follow contr
law, contravened Congressional purpose,
therefore, must be reversed.

CONCLUSION

For the foregoing reasons, the petition should be granted and the decision of the First Circuit below should be reversed.

Respectfully submitted,

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August 31, 2012

AMICUS CURIAE BRIEF

No. 12-142

In the Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
PETITIONER

v.

KAREN L. BARTLETT, RESPONDENT

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR MORTON GROVE PHARMACEUTICALS, INC., AUROBINDO PHARMA USA, INC., AMNEAL PHARMACEUTICALS, LLC, TEVA PHARMACEUTICALS USA, INC., IMPAX LABORATORIES, INC., AND RANBAXY PHARMACEUTICALS INC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the First Circuit erred in holding—in clear conflict with this Court's decisions in *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011); *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312 (2008); and *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992)—that federal law does not preempt state law design-defect claims against generic pharmaceutical products because, despite the conceded conflict between such claims and the federal laws governing generic pharmaceutical design, the makers of generic pharmaceuticals can simply stop making their products.

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INTRODUCTION AND INTEREST OF *AMICI CURIAE*

Recognizing that the Hatch-Waxman Act requires generic and brand-name drugs to carry the "same" labels—which generic manufacturers may not change—this Court recently held that federal law preempts state-law failure-to-warn claims against generics. *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2572 (2011). Despite *Mensing*'s sameness rationale, and its recognition that generics likewise must be "identical in active ingredients, safety, and efficacy" (*id.* at 2574 n.2), the court below held that state design-defect claims against generics are *not* preempted. The court offered no basis for distinguishing between failure-to-warn and design-defect claims. Yet it reasoned that the conceded conflict between such claims and federal law can be avoided because generic drug makers "can choose not to make the drug at all." Pet. App. 10a.

As confirmed by a host of conflicting decisions (see Pet. 25-26), this ruling ignores both the sameness rationale of *Mensing* and its result. After all, the conflict between the federal labeling requirements and state tort duties equally could have been avoided if the generics had chosen "not to make the drug at all." But it is worse than that: To the extent there is any basis for distinguishing between labeling-based and design-based claims for federal preemption purposes—and again, the court below failed to identify one—

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* Pursuant to Rule 37.2(a), *amici* provided timely notice of their intention to file this brief, and all parties have consented. The letters of consent are on file with the Clerk. In accordance with Rule 37.6, *amici* state that no counsel for any party authored this brief in whole or in part, and that no person or entity, other than the *amici*, contributed monetarily to the preparation or submission of this brief.

the case for federal preemption is even stronger in this context. As explained in Part I, labels do not exist for their own sake. They are signposts concerning the *product* on the inside of the container. That is, generic labels must track their FDA-approved brand counterparts for a reason—namely, that the generic products represented by the labels likewise must be the same as their brand counterparts. And since labels merely serve as a proxy for their products, *Mensing* necessarily requires preemption. The First Circuit's contrary view not only runs afoul of the Hatch-Waxman Act; it is analytically incoherent.

Amici curiae are manufacturers of generic drugs and defendants in thousands of suits seeking to impose liability upon them under state-law standards with which they have no ability to comply. The concern of these *amici* is that the state-by-state approach to labeling rejected in *Mensing* not be revived under a new name. By disregarding the essential unity between labels and products, the decision below exposes generic drug-makers to the same conflicting state law duties already rejected in *Mensing*. That is not what Congress intended when it commanded that a generic drug be a "copy" of the brand. The Court should grant the petition, summarily reverse the appellate court's refusal to follow *Mensing*, and restore the uniformity among lower courts that existed before the appellate court's aberrant decision in this case.

If that were not enough, preemption is required here for another reason. As shown in Part II, it is well settled that design-defect claims such as those at issue here are especially suited for federal regulation. Manufacturers and the economy suffer when complex products that are sold nationwide and extensively regulated at the federal level must submit to an additional layer of "diverse, nonuniform, and confusing

* * * regulations." *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 514 (1992). Indeed, where product design is not regulated uniformly, one State—even one *jury*—can effectively impose a controversial design upon the entire nation. And as this Court has consistently observed, "one State's power to impose burdens on the interstate market" is "constrained by the need to respect the interests of other States." *BMW, Inc.* v. *Gore*, 517 U.S. 559, 571 (1996). Far from imposing such burdens, the Hatch-Waxman process at issue here "is designed to *speed* the introduction of generic drugs to market." *Caraco Pharm. Labs, Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (emphasis added). That being so, federal law will not allow juries to decide that a generic drug ruled safe and effective by FDA must be banned outright, thus multiplying costs and slowing the drug's introduction in the remaining States.

As shown in Part III, the petition should also be granted to prevent problems beyond the generic drug industry. By the First Circuit's lights, there can be no preemption where a manufacturer can choose "not to make [its] [product] at all." Pet. App. 10a. But if that "choice" allowed plaintiffs to skirt preemption, then conflict preemption could never be established for federally regulated manufacturers. *Any* conflict between state tort law and federal requirements—whether related to labeling, packaging, design, or otherwise—can be avoided by ditching the product. Not surprisingly, this Court has repeatedly found conflict preemption despite the availability of a "choice" to cease marketing the allegedly defective product. *E.g.*, *Geier* v. *Am. Honda Motor Co., Inc.*, 529 U.S. 861 (2000); *Cipollone*, 505 U.S.at 514.

Sensing the reach of its decision, the First Circuit stated that this case presents "a question of excep-

tional importance." Pet. App. 8a. We agree. By exposing generic manufacturers to the same failure-to-warn claims rejected in *Mensing*—now dressed up as design-defect claims—the decision below puts generic manufacturers in an impossible situation. As the First Circuit itself recognized, generic manufacturers have no options: They can market a drug that complies with federal law (*i.e.*, one that has the same design as the name-brand equivalent), or they can drop the product. If allowed to stand, therefore, the decision below will make generic drugs both more expensive and more scarce—directly undermining Congress's intention in passing Hatch-Waxman.

For all these reasons, the Court should grant the petition, quash the First Circuit's resistance to the *Mensing* mandate, and reaffirm that state-law design claims against generic drugs are categorically preempted.

STATEMENT

This case involves a collateral attack on the label of an FDA-approved prescription drug, after this Court in *Mensing* (in the words of the court below) "foreclosed a direct attack on the adequacy of the label." Pet. App. 4a. The drug at issue, sulindac, is a non-steroidal anti-inflammatory product manufactured by petitioner. Pet. App. 1-4a. Respondent suffered injuries and filed suit against petitioner after she was prescribed sulindac by her doctor, who "admitted that he had not read the box label or insert." Pet. App. 4a.

Respondent alleged that petitioner's product was defectively designed. When petitioner responded that federal law required its generic sulindac to be a *copy* of the branded drug, and that any design-defect claim

was therefore preempted, the district court disagreed. According to that court, "one way to avoid violating state law * * * would be to refrain from distributing [the drug] at all." Pet. App. 165a. At trial, respondent's primary design-defect theory was that sulindac's risk exceeded its benefits, rendering it unreasonably dangerous. Pet. App. 4a. The jury agreed.

While petitioner's appeal was pending, this Court held that federal law preempts state-law failure-to-warn claims against generic pharmaceuticals in light of the "ongoing federal duty of sameness" requiring that generic drugs copy their brand-name counterparts. *Mensing*, 131 S. Ct. at 2574-2575 & n.2. The upshot of the federal sameness requirements here, petitioner argued, was that petitioner could not comply with state law (as applied by the jury) by selling a version of sulindac materially different than the FDA-approved, branded version.

The First Circuit agreed that petitioner "cannot legally make sulindac in another composition," but, like the district court, reasoned that petitioner "can choose not to make the drug at all; and the FDCA might permit states to tell [petitioner] it ought not be doing so * * * despite what the Supreme Court made of similar arguments in the labeling context." Pet. App. 10a. The court acknowledged that "[t]his is second-guessing the FDA," but justified its decision on the basis of *Wyeth* v. *Levine*, 555 U.S. 555, 575 (2009), which stated that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Pet. App. 9a.

The court below further recognized that *Mensing* post-dated *Wyeth* and, because of the generic sameness requirement, required preemption of failure-to-

warn claims. Indeed, it recognized that *Mensing* distinguished *Wyeth* on the basis that, unlike generics, a brand-name drug maker could "unilaterally strengthen its warning without prior FDA approval." 131 S. Ct. at 2581; Pet. App. 9a-10a. Yet the court insisted that *Mensing* was a narrow, "carved out" exception to the "general no-preemption rule" of *Wyeth*. Pet. App. 9a, 11a. Suggesting that its hands were tied, the court said it was "up to the Supreme Court to decide whether *Mensing*'s exception is to be enlarged to include design defect claims." Pet. App. 11a.

REASONS FOR GRANTING THE PETITION

In addition to those stated by petitioner, the petition should be granted for three reasons. *First*, the First Circuit's distinction between design-defect and failure-to-warn claims is not only foreclosed by the Hatch-Waxman Act, logic, and binding precedent, but if allowed to stand would upset the basic economic structure of the generic drug industry. *Second*, of all state-law claims challenging complex products that are sold in a national market and heavily regulated at the federal level, design-defect claims are particularly suited for preemption. *Third*, left undisturbed, the First Circuit's rationale would destroy the doctrine of conflict preemption as applied to manufacturers of federally regulated products. Indeed, so clear is *Mensing* and so flagrant the First Circuit's failure to follow it that the decision below warrants summary reversal.

I. By distinguishing between design-defect and failure-to-warn claims, the First Circuit misconceived both the text and structure of the Hatch-Waxman Act and the nature and economics of the generic drug industry.

According to the First Circuit, "it is up to the Supreme Court to decide" whether the rule of *Mensing* should be "enlarged" to cover design-defect claims. Pet. App. 11a. But no "enlarging" was needed. Not only does the reasoning of *Mensing* directly apply here, as the court below recognized (Pet. App. 10a), it applies *a fortiori*. Summary reversal is warranted.

A. Hatch-Waxman requires a generic drug to be designed as a copy of a brand-name drug, and thus identical in active ingredients.

As the First Circuit itself observed, under Hatch-Waxman, "[petitioner] cannot legally make sulindac in another composition" from that of the brand. Pet. App. 10a. Yet the court failed to draw the proper conclusion from this basic premise. Here is why.

1. For new drugs (*i.e.*, brand-name products), a manufacturer must submit a new drug application (NDA) establishing that the drug is safe and effective when used as labeled. 21 U.S.C. § 355(b); 21 C.F.R. § 314.50. To that end, an NDA must include the following: (1) data demonstrating that the drug is safe and effective; (2) analysis of the drug's composition; (3) an explanation of the methods and controls used for manufacturing, processing, and packing the drug; and (4) proposed labels. 21 U.S.C. § 355(b)(1)(A)-(F); 21 C.F.R. § 314.50(d)-(f). Further, before filing an NDA, the brand-name manufacturer must be authorized to conduct clinical trials to establish the drug's

safety and efficacy. 21 U.S.C. § 355(i); 21 C.F.R. §§ 312.2, 312.20.

The NDA process is exhaustive. A typical NDA spans thousands of pages and is grounded in clinical trials conducted over several years. GAO, *New Drug Development, Report to Congressional Committees*, 26 Biotech. L. Rep. 82, 94 (2007). On average, evaluating an NDA takes FDA some 442 days. *Id.* at 86.

The abbreviated ("ANDA") process for generic drugs is very different. "Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Caraco*, 132 S. Ct. at 1676 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)). That is, a generic is "designed to be a copy" of the brand-name drug. *Mensing*, 131 S. Ct. at 2574 n.2; Pet. 8-9.

To ensure safety, the generic copy must be "identical" to an approved NDA drug with respect to active ingredient, route of administration, dosage form, strength, and conditions of use. 21 U.S.C. § 355(j)(2)(A)(i); 21 C.F.R. § 314.92(a)(1).[1] Moreover,

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[1] In limited circumstances and subject to FDA's discretion, the ANDA process may also be used for a drug with one different active ingredient, or whose route of administration, dosage form, or strength differs from the NDA product. 21 U.S.C. § 355(j)(2)(C); 21 C.F.R. § 314.93; see generally 57 Fed. Reg. at 17951-17952. No such difference is involved in this case, much less factored into the decision below. In addition, as discussed below (at 19-20), the Court in *Mensing* considered and unequivocally rejected the argument that conflict preemption can be defeated based on what a generic manufacturer *could have* asked FDA to do, and how FDA *could have* responded. 131 S. Ct. at 2578-2579.

an ANDA must establish that the generic drug is therapeutically equivalent or "bioequivalent" to, and will be given the same labeling as, the brand-name drug. 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94(a). Use of the same label is critical because "[d]rug labeling serves as the standard under which FDA determines whether a product is safe and effective." 50 Fed. Reg. 7452, 7470 (Feb. 22, 1985).

Generic manufacturers need not (and do not) provide clinical evidence of safety or efficacy. That has already been done by the brand; no trials are needed to ensure the safety and efficacy of the copy. Rather, as this Court has repeatedly recognized, the point of Hatch-Waxman was "to speed the introduction of low-cost generic drugs to market." *Caraco*, 132 S. Ct. at 1676 (citing *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990)).[2] Congress thus directed FDA to approve any product that is a true generic—*i.e.*, bioequivalent to the branded drug and sold with identical labeling. The FDA will reject any ANDA drug that flunks these criteria. 21 C.F.R. § 314.127.

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[2] See also, *e.g.*, "P.L. 98-417, Drug Price Competition and Patent Term Restoration Act," H.R. Rep. No. 857(I), 98th Cong., 2d Sess. (1984), reprinted in 1984 U.S.C.C.A.N. 2647, Pet. App. 122a; New Drug Application: Hearings on H.R. 3605 Before the Subcomm. On Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong., 1st Sess. (1983), Pet. App. 114a; Drug Price Competition and Patent Term Restoration Act of 1984, Committee Notes, 130 Cong. Rec. 24416, H.R. 3605 (Sept. 6, 1984), Pet. App. 136a; Drug Price Competition and Patent Term Restoration Act, Committee Notes, 130 Cong. Rec. 24970, S. 1538 (Sept. 12, 1984).

In short, to the extent that state tort law may impose a different standard for the design of an FDA-approved drug, it is impossible for a generic manufacturer to comply. Whatever choices a brand-name manufacturer may have, the generic manufacturer has none. The ANDA product must be same as the NDA product; the generic manufacturer's federal obligations are as simple as that.

2. The court below did not adopt a different reading of these straightforward federal requirements. Instead, it declared that generic manufacturers have a "choice": Although federal law imposes a duty of "sameness" on generic products, in any State where a jury concludes that the law requires a different design than that adopted by the brand-name manufacturer and approved by the FDA, the generic manufacturer can simply cease doing business. Pet. App. 10a.

This analysis is flatly inconsistent with established principles of conflict preemption and both the rationale and result of *Mensing*, where the very same arguments were made and rejected. See Pet. 27-30. It also threatens to overthrow Congress's carefully calibrated approach to introducing generic drugs, which gave birth to the generic drug industry. And "it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public." *Mensing*, 131 S. Ct. at 2582.

To this day, generic companies stay in business only because of the lower costs of the streamlined Hatch-Waxman process. "While estimates of the cost to bring a new branded drug to market are in excess of a billion dollars, the research and development costs for a new generic drug are only 1 to 2 million

dollars." ASPE Issue Brief: Office of the Assistant Secretary for Planning & Evaluation, Office of Science and Data Policy–U.S. Department of Health and Human Services, *Expanding the Use of Generic Drugs* 4-5 (Dec. 2010).[3] Moreover, "[t]he relatively low costs to entry for generic drugs lead to increased competition, which drive prices for generic drugs down dramatically." *Id.* at 5. And "growth in the use of generic drugs has generated substantial savings for American consumers"—savings recently estimated to be $139.6 billion. *Id.* at 2, 6.

But if generics are shut out from marketing in various States—the lower court's "solution" to the federal-state conflict here—these savings will dwindle and could put generics out of business. At a minimum, the ruling below threatens to work fundamental changes in the way generics do business—including by multiplying their costs—to the ultimate detriment of consumers and the nation's health care system. That result would be squarely at odds with the purpose of the Hatch-Waxman Act.

That Act is "the supreme law of the land," "anything in the constitution or laws of any state to the contrary notwithstanding." U.S. Const. Art. VI, Cl. 2. And again, the First Circuit conceded that generics "cannot legally" differ from their brand counterparts. Pet. App. 10a. Yet it affirmed a jury verdict imposing liability based on petitioner's failure to do precisely that—depart from the brand-name design. For this reason alone, the petition should be granted and the judgment below summarily reversed.

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[3] Available at: http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.shtml.

B. The notion that failure-to-warn claims are preempted but design defect claims are not is analytically incoherent.

The decision below is also analytically incoherent. Drug product design drives labeling, not the other way around. As the FDA has instructed, "the ANDA product's labeling must be the same as the listed drug product's labeling *because the listed drug product is the basis for ANDA approval.*" FDA, Abbreviated New Drug Application Regulations—Final Rule, 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992) (emphasis added); see also *Mensing*, 131 S. Ct. at 2574 (describing parallel sameness requirements for generic products and labels).

For this reason, a label no more controls product design than a tail wags a dog. To say, as did the court below, that a state law claim against a *label* is preempted, but a claim against the *product* design is not, is fundamentally to misunderstand the nature of the label-product relationship. Indeed, it is to get that relationship exactly backwards. If the labeling claim is preempted, the design-defect claim must be preempted, because the label is merely a proxy for the product. The reason a generic's label must track the brand's label verbatim is that the product must likewise be "the same as" the branded product.

Just last Term, in finding preemption under another federal statute, this Court recognized the close relationship between failure-to-warn and design-defect claims. See *Kurns* v. *Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1268 (2012) (noting that "[a] failure-to-warn claim alleges that the product itself is unlawfully dangerous unless accompanied by sufficient warnings or instructions" and explaining that,

where "failure-to-warn claims are * * * directed at the equipment [at issue], the "'gravamen' of [those] failure to warn claims" is sufficiently similar to warrant preemption under the same rationale). Indeed, many jurisdictions (including New Hampshire, where this case originated) recognize that an adequate warning is sufficient to defeat design-defect claims. Pet. 7a; *Fellows* v. *USV Pharm. Corp.*, 502 F. Supp. 297, 300 (D. Md. 1980) (collecting cases establishing that "prescription drugs are not considered unusually dangerous under section 402A, and the manufacturer will not incur liability under that section, unless the manufacturer has failed to provide adequate warnings of the drug's possible dangers").

As the Second Restatement of Torts explains, a product may be "unavoidably unsafe," a classification "common in the field of drugs," which often have undesirable side-effects and carry serious risks. "Such a product, properly prepared and accompanied by proper directions and warning, is not defective." Restatement (Second) of Torts § 402A cmt. k; see also *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068, 1077 (2011) ("Comment k exempts from * * * strict-liability rule 'unavoidably unsafe' products."). The reason is that the potential downsides of such drugs are not a product of bad design; they are simply an unavoidable risk. In fact, the First Circuit itself acknowledged that, under New Hampshire law, claims of design-defects can collapse into claims of failure-to-warn. Pet. App. 7a.

* * * * *

In short, in the context of prescription drugs, "design-defect" claims are a red herring. There is no meaningful distinction between such tort claims and

claims for failure-to-warn: The law requires generic labels *and* products to match their brand counterparts; labels are derived from the products, not vice versa; and the adequacy of product warnings (which *Mensing* immunizes from challenge in the context of generic drugs) is a complete defense to design defect liability. It is telling that the court below did not propose any rationale whatsoever for distinguishing these two types of claims in substance. But given that any attack on the drug labels here is preempted under *Mensing*, preemption of any attack on their corresponding products should be a foregone conclusion—as every other court had recognized before the ruling below. In reaching a contrary conclusion, the decision below is not only unlawful and analytically unsound, it is also destabilizing to the generic drug industry and threatens significant costs to consumers and the nation's health care system. For this reason alone, the petition should be granted and the decision below summarily reversed.

II. State tort claims challenging the design of complex products that are heavily regulated by the federal government and sold in a national market are particularly suited for preemption.

The decision below is particularly worthy of review and reversal because, of all types of tort claims, design defects—particularly of pharmaceuticals—are among those most worthy of preemption. Yet instead of *federal preemption*, the First Circuit authorized *state prohibition*. This turns the law of supremacy on its head, and threatens to deprive citizens in "prohibition States" of drugs that FDA has approved, while adding to the burdens on manufacturers attempting to serve a national market.

1. For complex products that are mass-produced, easily transported, and heavily regulated at the federal level, a patchwork quilt of additional state regulation is quite problematic. It raises the costs of compliance and makes it difficult for consumers to discern what is safe and what is not. See, *e.g.*, James A. Henderson, Jr., *Judicial Review of Manufacturer's Conscious Design Choices: The Limits of Adjudication*, 73 Colum. L. Rev. 1531, 1576 (1973) ("the legislative and administrative processes are institutionally suited" to "establishment of specific design standards."); Michael W. McConnell, *A Choice-of-Law Approach to Products-Liability Reform*, in New Directions in Liability Law, 37 Proceedings of the Acad. of Political Science 90, 91 (1988) ("[s]ince most products are made in one state and used in another, at least two states are usually involved," and "they will not all be able to get their way when their laws differ"). Likewise, the national economy is weighed down if manufacturers of national products that are already closely controlled by federal rules must submit to "diverse, nonuniform, and confusing * * * regulations." *Cipollone, Inc.*, 505 U.S. at 514. For these reasons, numerous courts have recognized the "need for national uniformity in product regulation." *E.g.*, *Horn* v. *Thoratec Corp.*, 376 F.3d 163, 176 n.20 (3d Cir. 2004); *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 797 (8th Cir. 2001).

This is particularly true where the product is as sophisticated as the chemical drug compounds at issue here. If there is a problem with the design of a pharmaceutical, it cannot be fixed by adding, say, a simple safety guard or turn-off switch. The costs of re-engineering drugs is astronomical, which is one reason why Hatch-Waxman prescribes that a generic

drug be a copy of the brand. But while the First Circuit seemed to grasp the impossibility of changing a drug's design (Pet. App. 10a), the court's cure—entirely removing the product from the market—was worse than the alleged disease. Rather than allowing juries to create a patchwork quilt of standards (which would have been forbidden as well), the decision below would allow juries to create a patchwork quilt of *prohibitions*.

Make no mistake: If "[t]he obligation to pay compensation" is "a potent method of governing conduct and controlling policy" (*Kurns*, 132 S. Ct. at 1269, (quoting *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959)); accord *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 324 (2008)), it is likewise potent to drive a product out of a State market entirely. Unlike brand-name drugs, generics typically have a thin profit margin—which means both that a single jury verdict on the order of the one here ($21 million, for a single plaintiff) may demand abandoning a given market. Further, being shut out from entire markets can be a company killer, particularly for small companies. In *Buckman Co.* v. *Plaintiffs' Legal Committee*, the Court recognized that the "fear" of "expos[ing] the manufacturer * * * to unpredictable civil liability" might "discourage [applicants] from seeking § 510(k) approval of devices." 531 U.S. 341, 350 (2001). So too may the prospect of being forced to drop products entirely in various States deter the development of needed low-cost generic medicines.

Allowing design-defect claims would also permit juries in 50 different States to reach judgments that differ from the FDA's—and from each other's. As the Court recognized in *Garner* v. *Teamsters*, 346 U.S. 485, 490-491 (1953), "[a] multiplicity of tribunals and

a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law." Citing this danger, *Buckman* explained that allowing liability under "50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress." 531 U.S. at 350. The same is true of the design-defect claims here.

Indeed, because drugs cross state lines, the ruling below effectively allows the most pro-ban State to set policy for the whole nation, undermining the Act's goal of quickly getting generic drugs to the national market. But "one State's power to impose burdens on the interstate market" is "constrained by the need to respect the interests of other States." *BMW*, 517 U.S. at 571. And where, as here, "[t]he subject-matter * * * peculiarly * * * calls for uniform law," States should not be permitted to "supplement" federal mandates, much less overrule them outright. *Penn. R.R.* v. *Public Serv. Comm'n*, 250 U.S. 566, 569 (1919). Yet that is exactly what the decision below accomplishes in allowing States to blacklist products that the FDA, after extensive study, has deemed safe and effective.

2. As this Court has recently emphasized in the context of medical device liability, these problems are further exacerbated where, as here, a ruling authorizes a ban to be imposed "by juries." *Riegel*, 552 U.S. at 325. The problem is that juries simply are not constituted or equipped to regulate products such as those at issue here:

> A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by

> the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.

Ibid. Similarly, as the Eighth Circuit has observed, "[i]t would be difficult for a jury focused on a single case to take into account 'the cumulative, systemic effects' of a series of verdicts. In contrast, the FDA possesses a broader perspective.'" *Brooks*, 273 F.3d at 797 (quoting Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 Geo. L.J. 2167, 2175 (2000)).

In enacting Hatch-Waxman, Congress acted to replace a patchwork of state tort standards with a uniform, feasible, safe, and economically sound set of rules established by an expert agency and imposed on a prospective basis. It is not juries, but FDA, that is charged with determining whether a product is safe and effective, and hence whether its benefits outweigh its risks. The involvement of juries is "not required or even suggested" by the Act, and the courts should not "turn somersaults" to create it. *Riegel*, 552 U.S. at 325. In light of *Mensing*, however, turning somersaults is an apt description of the approach taken below. As the court itself acknowledged, it was "second-guessing the FDA." Pet. App. 10a; *cf. Geier*, 529 U.S. at 882 (rejecting attempt to show lack of conflict based on suggestion that manufacturer could have complied with state law by selling "a *different* kind of" product) (emphasis in original).

Review is needed to prevent this type of admitted second-guessing of the expert agency, contrary to the statutory scheme, as to a species of tort claim especially well-suited for uniform federal regulation.

III. Taken to its logical conclusion, the First Circuit's rationale would eliminate all application of the doctrine of conflict preemption to claims against manufacturers in federally regulated industries.

Review is needed for a third reason as well. Left uncorrected, the First Circuit's decision would destroy the doctrine of conflict preemption as applied to federally regulated industries.

According to the First Circuit, a generic "certainly can choose not to make the drug at all; and the FDCA might permit states to tell [petitioner] it ought not be doing so if risk-benefit analysis weighs against the drug." Pet. App. 10a. But just this kind of counterfactual argument was rejected in *Mensing*. And if it were the law, a host of this Court's preemption decisions would have come out the other way.

The plaintiff in *Mensing* contended that, "if the Manufacturers had asked the FDA for help in changing the corresponding brand-name label, they might eventually have been able to accomplish under federal law what state law requires." 131 S. Ct. at 2578. That is, if the Manufacturers had asked, "and if the FDA decided" to help, "and if the FDA undertook negotiations," "and if adequate label changes were decided on and implemented, then the Manufacturers would have started a Mouse Trap game that eventually led to a better label." *Ibid.*

This Court refused to accept that "conflict preemption should take into account these possible ac-

tions." *Ibid.* Instead, it held that "[t]he question for 'impossibility' is *whether the party could independently do under federal law what state law requires of it.*" *Id.* at 2579 (emphasis added). In other words, the law of preemption assumes stasis: The regulated party keeps producing the same product; and the federal government keeps enforcing the same law.

To assume away one of these fixed assumptions is to render any resulting harmony in the law illusory. As the Court put it in *Mensing*, "[i]f these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict preemption all but meaningless." 131 S. Ct. at 2579. Similarly, the Court in *Geier* rejected an attempt to show the lack of a conflict based on the notion that the manufacturer could have complied with state law by selling "a *different* kind of" product. 529 U.S. at 882 (emphasis in original).

Such conjectures contain no limiting principle. No matter how clear an agency tries to be—even forbidding requests for rule changes themselves—the plaintiff could always say, "But 'they did not even try to start the process'" that might have alleviated the conflict. 131 S. Ct. at 2579. There would be no rational basis for preventing this infinite regression of one-upsmanship. See *Mensing* Oral Arg. Tr. 38:8-15 (Alito, J.) ("[S]uppose that the FDA issued a rule that says a generic drug manufacturer has no obligation to request a change in labeling. Could a generic drug manufacturer be held liable on a failure to warn claim on the theory that it could have lobbied the

FDA to change the rule that says that the generic drug manufacturer has no obligation to ask for a change in labeling?").

The First Circuit took exactly the path forbidden in *Mensing*. To prevent federal and state law from conflicting, it relied on conjectures of the worst kind: assuming the generic abandoned its product. Pet. App. 10a. Insofar as abandoning the product is *always* an option, that view leaves conflict preemption without any force.

This holds true across federally regulated industries. Whether it is the automobile industry (*Geier*), the cigarette industry (*Cipollone*), the generic drug industry (*Mensing*), or others, it is untenable to say that the solution to federal-state conflicts is simply to stop making products. And if *Mensing* can be distinguished in this way, then so too can *Geier*, *Cipollone*, and like cases. The decision below threatens to render these precedents dead letters, as the response to every defense of conflict preemption involving a federally regulated product will be simple: Pull the product from the market. For this reason too, the decision below demands review and reversal.

CONCLUSION

If federal supremacy is to mean anything, States must not be permitted to ban products whose compliance with the mandates of federal law brings them into direct conflict with state standards. The petition should be granted, and the judgment below summarily reversed.

Respectfully submitted.

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JOINT APPENDIX

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IN THE

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MUTUAL PHARMACEUTICAL COMPANY, INC.,

Petitioner,

v.

KAREN L. BARTLETT,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

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Summary Order on Plaintiff's Negligence Claim
Dkt. No. 329
August 11, 2010 ..... JA 315

Summary Order on Plaintiff's Motion to Exclude Evidence from Trial
Dkt. No. 335
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Summary Order Denying Mutual Pharmaceutical Corporation's Second Motion for Reconsideration
Dkt. No. 336
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FDA Decision Memo, Trial Exhibit 905 ..... JA 557

Excerpts from Deposition of Dr. Robert Stern
page 175 (Feb. 15, 2010) ..... JA 594

Park, G., *et al.*, *Serious Adverse Reactions Associated With Sulindac*, Arch. Intern. Med., vol. 142, excerpts of pp. 1292, 1294 (July 1982) ..... JA 596

Stern, R., *et al.*, *An Expanded Profile of Cutaneous Reactions to Nonsteroidal Anti-Inflammatory Drugs*, JAMA, vol. 252, no. 11, excerpts of pp. 2480, 2482 (Sept. 1984) ..... JA 603

Bigby, M., *et al.*, *Allergic Cutaneous Reactions to Drugs*, Primary Care, vol. 16, no. 3, excerpts of pp. 713, 718-720 (Sept. 1989) (excerpts) ..... JA 614

Wolkenstein, P., *et al.*, *Drug-Induced Toxic Epidermal Necrolysis*, Clinics in Dermatology, excerpts of pp. 399, 401-02, 403-04 (1998) ..... JA 609

Shulz, J.T., *et al.*, *A 10-Year Experience With Toxic Epidermal Necrolysis*, Journal of Burn Care & Rehabilitation, excerpt of p. 199 (2000) ..... JA 624

Stern, R., *et al.*, *Analysis and Prevention of Data that assess the Risk of Stevens-Johnson Syndrome and toxic epidermal necrolysis associated with*

nonsteroidal anti-inflammatory drugs, excerpts of pp. 1, 10-12, 15-17, 23-25 (Oct. 2001) ..... JA 626

La Grenade, *et al.*, *Comparison of Reporting of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Association with Selective COX-2 Inhibitors*, Drug Safety, experts from pp. 917-18, 922-23 (2005) ..... JA 635

Selected photos of Karen Bartlett ..... JA 640

RELEVANT DOCKET ENTRIES

United States District Court
For the District of New Hampshire

Case No. 08-CV-358-JL

Bartlett v. Mutual Pharmaceutical Company, Inc.

Date Filed	#	Docket Text
08/28/2008	1	NOTICE OF REMOVAL with Jury Demand from Rockingham County Superior Court, case number 08-c-33. (Filing fee $350) Receipt No. 0102000000000 0435248 filed by Karen L. Bartlett, Gregory S. Bartlett. Answer due by 9/22/2008. State Court Record due by 9/15/2008. (Attachments: # 1 State Court Record, # 2 Notice of Removal to Counsel, # 3 Defendant's Notice of Removal, # 4 Affidavit of John Friberg, # 5 Civil Cover Sheet) (amm) (Entered: 09/02/2008)
09/05/2008	6	Addendum/Exhibits A, B, C, D, and E to 1 Notice of Removal - New Case, by Mutual Pharmaceutical Company, Inc. (Attachments: # 1 Exhibit Notice of Removal Exhibit A, # 2 Exhibit Notice of Removal Exhibit B-1, # 3 Exhibit Notice of

		Removal Exhibit B-2, # 4 Exhibit Notice of Removal Exhibit B-3, # 5 Exhibit Notice of Removal Exhibit C, # 6 Exhibit Notice of Removal Exhibit D, # 7 Exhibit Notice of Removal Exhibit E) (Friberg, John) (Entered: 09/05/2008)
09/18/2008	11	ANSWER to Complaint with jury demand filed by Mutual Pharmaceutical Company, Inc. (Friberg, John) (Entered: 09/18/2008)
12/03/2008	44	MOTION to Dismiss *Based on Federal Preemption* filed by Mutual Pharmaceuticals Company, Inc., United Research Laboratories, Inc. Follow up on Objection on 12/22/2008. (Attachments: # 1 Memorandum of Law in Support of Defendants' Motion to Dismiss Based on Federal Preemption, # 2 Exhibit (Affidavit) of Linda E. Maichl in Support of Motion to Dismiss Based on Federal Preemption, # 3 Exhibit 1 drug approval history, # 4 Exhibit 2 - P.L. 98-417, # 5 Exhibit 3-1 New Drug Application 1983, # 6 Exhibit 3-2 New Drug Application 1983, # 7 Exhibit 4-1 - Drug Price Competition 9-6-84, # 8 Exhibit 4-2 - Drug Price Competition 9-6-84, # 9 Exhibit 5 Drug Price Competition 9-12-84, # 10 Exhibit 6-1 57 Fed Reg 17950, # 11 Exhibit 6-2 - 57 Fed Reg 17950, #

		12 Exhibit 7 - 48 Fed Reg 2751, # 13 Exhibit 8 A Special Report from FDA, # 14 Exhibit 9 FDA's CDER Handbook, # 15 Exhibit 10-1 50 Fed Reg 7452, # 16 Exhibit 10-2 - 50 Fed Reg 7452, # 17 Exhibit 10-3 - 50 Fed Reg 7452, # 18 Exhibit 11 Postmarketing Survelliance Programs, # 19 Exhibit 12 21 C.F.R. 201.56, # 20 Exhibit 13 21 C.F.R. 201.57, # 21 Exhibit 14 71 Fed Reg 3922) (Maichl, Linda) Modified on 9/30/2009 to add: (kat). (Entered: 12/03/2008)
12/03/2008	45	Exhibit *15-1 44 Fed Reg 37434* to 44 MOTION to Dismiss *Based on Federal Preemption* by Mutual Pharmaceutical Company, Inc., Untied Research Laboratories, Inc. (Attachments: # 1 Exhibit 15-2 44 Fed Reg 37434, # 2 Exhibit 16-1 - 65 Fed Reg 81082, # 3 Exhibit 16-2 - 65 Fed Reg 81082, # 4 Exhibit 17-1 54 Fed Reg 28872, # 5 Exhibit 17-2 - 54 Fed Reg 28872, # 6 Exhibit 17-3 - 54 Fed Reg 28872, # 7 Exhibit 17-4 - 54 Fed Reg 28872, # 8 Exhibit 18 Guidance for Industry November 1999, # 9 Exhibit 19 Guidance for Industry May 2000, # 10 Exhibit 20 - 30 Fed Reg 993, # 11 Exhibit 21 73 Fed Reg 2848, # 12 Exhibit 22-1 47 Fed Reg 46622, # 13 Exhibit 22-2 47 Fed Reg 46622, # 14 Exhibit 23 - FDA Amicus Colacicco 5-10-06, # 15

		Exhibit 24 FDA Amicus Colacicco 12-4-06, # 16 Exhibit 25 FDA Letter Brief Perry, # 17 Exhibit 26 - 73 Fed Reg 49603, # 18 Exhibit 27-1 FDA Amicus Wyeth v Levine, # 19 Exhibit 27-2 FDA Amicus Wyeth v Levine) (Maichl, Linda) (Enter: 12/03/2008
12/03/2008	46	Exhibt 28 *Changes in Labeling of ANDAs to* 44 MOTION to Dimiss Basedon Federal Preemption, 45 Exhibit, by Mutual Pharmaceutical Company, Inc., United Reserachg Laboratories, Inc. (Attachments: # 1 Exhibit 29 Demahy v Wyeth, # 2 Exhibit 30 Kelly v. Wyeth, # 3 Exhibit 31 Laisure-Radke v Par, # 4 Exhibit 32 Sharp v. Leichus, # 5 Exhibit 33 - Goldych v. Eli Lilly, # 6 Exhibit 34 Mensing v. Wyeth, # 7 Exhibt 35 - Mensing v. Wyeth II, # 8 Exhibit 36 - McKenney v. Purepac, # 9 Exhibit 37 Morris v. Wyeth, # 10 Exhibit 38 Smith v. Wyeth, # 11 Exhibit 39 Wilson v. Wyeth, # 12 Exhibit 40 Bolin v. SmithKline, # 13 Exhibit 41 Masterson v. Apotex, # 14 Exhibit 42 Valerio v. SmithKline, # 15 Exhibit 43 - Gaeta v. Perrigo Pharmaceuticals, # 16 Exhibit 44 - Conte v. Wyeth 2-20-7, # 17 Exhibit 45 - Conte v. Wyeth 9-14-06) (Maichl, Linda) (Entered: 12/03/2008)

01/05/2009	50	RESPONSE to Motion re 44 MOTION to Dismiss *Based on Federal Preemption* filed by Karen L. Bartlett. (Attachments: # 1 Memorandum of Law Memorandum of Law, # 2 Exhibit (Affidavit) Exhibit (Affidavit) of Keith M. Jensen, # 3 Exhibit # 1 2005 FDA mandated label Sulindac, # 4 Exhibit # 2 Kellogg v. Wyeth, # 5 Exhibit #3 FDA Science & Mission at Risk, # 6 Exhibit #4 Dr. Cassell Testimony co author FDA at Risk, # 7 Exhibit #5 Congressional Investigators, # 8 Exhibit #6 GAO Report, # 9 Exhibit #7 21 USC 355, # 10 Exhibit #8 21 USC all rule of Const, # 11 Exhibit #9 21 CFR 601.12, # 12 Exhibit #10 21 CFR 314.70 thru 4.04, # 13 Exhibit #11 21 CFR 314.70 2006, # 14 Exhibit #12 Thomas' Losing Reply in Kellogg, # 15 Exhibit #13 21 CFR 201.57 '90-'05, # 16 Exhibit #14 21 CFR 314.70 2006, # 17 Exhibit #15 21 CFR 314.97 '04, # 18 Exhibit #16 21 CFR 314.97 '07, # 19 Exhibit #17 Congress Letter 2.23.06, # 20 Exhibit #18 Barnhill 2007, # 21 Exhibit #19 Kelly 2007, # 22 Exhibit #20 Laisure, # 23 Exhibit #21 Zikis, # 24 Exhibit #22 Delahoussaye 2007, # 25 Exhibit NEJM Amicus Brief in Levine, # 26 Exhibit #24 10.85 Advisory Opinions) (Jensen, Keith) (Entered: 01/05/2009)

01/06/2009	51	Notice of Intent to Reply to Objection to 44 MOTION to Dismiss *Based on Federal Preemption*. Follow up on Reply on 01/26/2009 (Maichl, Linda) (Entered: 01/06/2009)
01/23/2009	52	REPLY to Objection to Motion re 44 MOTION to Dismiss *Based on Federal Preempton* filed by Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc. (Maichl, Linda) (Entered: 01/23/2009)
03/06/2009	55	MOTION for Leave to File Supplemental Memorandum Concerning Supplemental Authority in Support of Motion to Dismiss Instanter filed by Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc.. Follow up on Objection on 3/23/2009. (Attachments: # 1 Exhibit 1-1 Levine v. Wyeth, # 2 Exhibit 1-2 Levine v. Wyeth, # 3 Exhibit 2 Morris v. Wyeth Notice et al.) (Maichl, Linda) (Entered: 03/06/2009)
03/25/2009	56	BRIEF/MEMORANDUM re Order on Motion for Leave to File, *Supplemental Memorandum Concerning Supplemental Authority in Support of Motion to Dismiss* by Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc. (Maichl, Linda) Modified on

		3/25/2009 to add: docket relationship to Motion 44 (dae) (Entered: 03/25/2009)
08/26/2009		Minute Order for proceedings held before Judge Joseph N. Laplante: MOTION HEARING held on 8/26/2009 re 44 MOTION to Dismiss *Based on Federal Preemtpion*. Court Order: Motion to Dimiss 44 denied. Written order to issue. (Court Reporter: Diane Churas) (Pltfs Atty: Keith Jensen, Bryan Ballew, Christine Craig) (Defts Atty: Joseph Thomas, Stephen Judge) (Total Hearing Time: 2 hours 9 minutes) (dae) (Entered: 08/27/2009)
09/30/2009	85	ORDER denying 44 Motion to Dismiss *Based on Federal Preemption*. So Ordered by Judge Joseph N. Laplante. (jb) (Entered: 09/30/2009)
01/17/2010	121	AMENDED COMPLAINT against all defendants with jury demand filed by Karen L. Bartlett. (Jensen, Keith) (Entered: 01/17/2010)
02/08/2010	123	*Mutual's Defenses and* ANSWER to 121 Amended Complaint with jury demand filed by Mutual Pharmaceutical Company, Inc. (Cosgrove, Paul) (Entered: 02/08/2010)
02/26/2010	131	MOTION for Summary Judgment filed by Karen L. Bartlett. Follow up

		on Objection on 3/31/2010. (Attachments: # 1 Memorandum of Law, 2 Exhibit (Affidavit) Affidavit of Keith M. Jensen, # 3 Exhibit A Sulindac 2.02 Label sent to FDA 5.03, # 4 Exhibit B Sulindac 7.05 Label obtained at Ehrreich depo, # 5 Exhibit C Sulindac 2.06 Label sent to FDA 5.07, # 6 Exhibit D Exh 49 Ergin Dep, # 7 Exhibit E Exh 50 Ergin Decl, # 8 Exhibit E Exh 1, # 9 Exhibit E Exh 2, # 10 Exhibit E Exh 3, # 11 Exhibit E Exh 4, # 12 Exhibit E Exh 5, # 13 Exhibit E Exh 6, # 14 Exhibit E Exh 7, # 15 Exhbit E Exh 8, # 16 Exhibit E Exh 9, # 17 Exhibit E Exh 10, # 18 Exhibit E Exh 11, # 19 Exhibit E Exh 14 Part 1, # 20 Exhibit E Exh 14 Part 2, # 21 Exhibit E Exh 14 Part 3, # 22 Exhibit E Exh 15 Part 1, # 23 Exhibit E Exh 15 Part 2, # 24 Exhibit E Exh 15 Part 3, # 25 Exhibit F Dep Ergin Tashin 8.11.09, # 26 Exhibit G Dettery Robert V1 8.28.09, # 27 Exhibit H Ehrreich V1 & V2, # 28 Exhibit I Stern Robert 2.15.10, # 29 Exhibit J 20157 eff thru 4.1.05, # 30 Exhibit K 314.8 thru 4.05, # 31 Exhibit L EuroScar NSAIDs & SJS-TEN, # 32 Exhibit M Valuck Robert, # 33 Exhibit N Fitpatrick's on Derm Aspirin has no risk of TEN, # 34 Exhibit O Publication - Label May Differ Btwn

		Gen and Brand, # 35 Exhibit P Dr. Charles Hoppes FDA 5.08 Pwr Pt, # 36 Exhibit Q Clinoril Label SE 51 Part 1, # 37 Exhibit Q Clinoril Part 2, # 38 Exhibit Q Clinoril Part 3) (Jensen, Keith) (Entered: 02/27/2010)
02/27/2010	132	NOTICE of Additional Exhibits to Plaintiff's Motion for Summary Judgment by Karen L. Bartlett. (Attachments: # 1 Exhibit E Exh 12 Part 1, # 2 Exhibit E Exh 12 Part 2, # 3 Exhibit E Exh 13 Part 1, # 4 Exhibit E Exh 13 Part 2, # 5 Exhibit R Karen Bartlett Depo, # 6 Exhibit S Dibenedetto Ergin 11.09) (Jensen, Keith) (Entered: 02/27/2010)
03/30/2010	145	MOTION for Summary Judgment *Based on Federal Preemption* filed by Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc. Follow up on Objection on 5/3/2010. (Attachments: # 1 Exhibit (Affidavit) Declaration of Cosgrove, # 2 Exhibit 1 Morrison Deposition, # 3 Exhibit 2 Pollock Deposition, # 4 Exhibit 3 Sporn Deposition, # 5 Exhibit 4 - Guidance-April 2004, # 6 Exhibit 5 69 Fed Reg 18728, # 7 Exhibit 6 - MAPP 5240.8) (Cosgrove, Paul) (Entered: 03/30/2010)
03/20/2010	146	MOTION for Summary Judgment filed by Mutual Pharmaceutical Company, Inc., United Research

		Laboratories, Inc. Follow up on Objection on 5/3/2010. (Attachments: # 1 Exhibit (Affidavit) Declaration of Cosgrove, # 2 Exhibit 1-K. Bartlett Deposition, # 3 Exhibit 2-1-K. Bartlett Medical Records, # 4 Exhibit 2-2- K. Bartlett Medical Records, # 5 Exhibit 2-3 K. Bartlett Medical Records, # 6 Exhibit 3 Brooks Pharmacy Advisor, # 7 Exhibit 4 Roujeau Article, # 8 Exhibit 5 Mutual's Supplemental Response to Production, # 9 Exhibit 6 Dettery Deposition, # 10 Exhibit 7 FDA Approval letter to Mutual, # 11 Exhibit 8 Mutual's Supplemental Answers to Interrogatories, # 12 Exhibit 9 Werynski Deposition, # 13 Exhibit 10 - Lux v. Teva Order, # 14 Exhibit 11 - Plaintiff's Answer to Mutual's Interrogatories) (Cosgrove, Paul) (Entered: 03/30/2010)
03/31/2010	149	OBJECTION to 131 MOTION for Summary Judgment filed by Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc. (Attachments: # 1 Exhibit (Affidavit) Declaration of Cosgrove, # 2 Exhibit 1 Ergin Deposition Excerpts, # 3 Exhibit 2 PDR Reference, # 4 Exhibit 3 Sulindac Label, # 5 Exhibit 4 Stern Deposition Excerpts, # 6 Exhibit 5 Stern Report, # 7 Exhibit 6 Brooks

		Pharmacy Advisor, # 8 Exhibit 7 K. Bartlett Deposition Excerpts, # 9 Exhibit 8 G. Bartlett Deposition Excerpts, # 10 Exhibit 9 Stern Supplemental Report, # 11 Exhibit 10 - Ehrreich Report, # 12 Exhibit 11 Dettery Deposition Excerpts, # 13 Exhibit 12 Salisbury Deposition Excerpts, # 14 Exhibit 13 - Werynski Deposition Excerpts, # 15 Exhibit 14 2/25/10 Email, # 16 Exhibit 15 Sadrnoori Deposition Excerpts, # 17 Exhibit 16 Chodosh Deposition Excerpts, # 18 Exhibit 17 Pliskow Deposition Excerpts, # 19 Exhibit 18 - Stern Errata Sheet, # 20 Exhibit 19 Ehrreich Deposition Excerpts, # 21 Exhibit 20 Plaintiff's Answer to ROGS, # 22 Exhibit 21 Notice of Deposition Duces Tecum, # 23 Exhibit 22 - DeBenedetto Disclosure, # 24 Exhibit 23 - Tackett Deposition Excerpts) (Cosgrove, Paul) (Entered: 03/31/2010)
04/13/2010	158	REPLY To Objection to Motion re 131 MOTION for Summary Judgment filed by Karen L. Bartlett. (Attachments: # 1 Exhibit A FDA Response to Salisbury Tackett Cit pet, # 2 Exhibit B 41 356h 200mg Signed forms thru 08.04 Part 1, # 3 Exhibit B 41 356h 200mg Signed forms thru 8.04 Part 2, # 4 Exhibit C Ergin signed Declaration 5.26.09, # 5 Exhibit D Ergin unsigned draft

		declarations Part 1, # 6 Exhibit D Ergin unsigned draft declarations Part 2, # 7 Exhibit E Email w. Bottle & Pill Pics) (Jensen, Keith) (Entered: 04/13/2010)
04/30/2010	166	SURREPLY to Reply to 131 MOTION for Summary Judgment filed by Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc. (Attachments: # 1 Exhibit (Affidavit) Declaration of P. Cosgrove in Support of Surreply, # 2 Exhibit Exhibit 1: Email from B. Ballew, Esq. to P. Cosgrove, Esq., # 3 Exhibit Exhibit 2: Excerpts of the Deposition of Plaintiff K. Bartlett) (Cosgrove, Paul) (Entered: 04/30/2010)
04/30/2010	167	OBJECTION to 146 MOTION for Summary Judgment *and Memorandum in Support* filed by Karen L. Bartlett. (Attachments: # 1 Exhibit (Affidavit) Declaration of Keith M. Jensen, # 2 Exhibit 1 Dep Ergin, Tahsin 8.11.09, # 3 Exhibit 2 Ergin signed Declaration 5.26.09, # 4 Exhibit 3 Ergin unsigned draft declaration, # 5 Exhibit 4 EuroScar NSAIDS & SJS-TEN, # 6 Exhibit 5 Fitpatirck's on Derm Aspirin, # 7 Exhibit 6 Dep of Valuck Robert, # 8 Exhibit 7 Tackett Randall Report, # 9 Exhibit 8 Salisbury Report and CV, # 10 Exhibit 9 Tackett R Vol. 1

		and Vol 2, # 11 Exhibit 10 Dep of Salisbury R, # 12 Exhibit 11 Dep of Stern, Robert, # 13 Exhibit 12 Dep of Schulz, John, # 14 Exhibit 13 Dep of Ryan, Colleen, # 15 Exhibit 14 Dep of Kim, Nam, # 16 Exhibit 15 Schulz TEN is a medication induced, # 17 Exhibit 16 50% TEN survivors disabling eye lesions, # 18 Exhibit 17 Dibenedetto-Ergin 11.09, # 19 Exhibit 18 Ergin Dep 2002 Sulindac Label, # 20 Exhibit 19 Clinoril Label SE 51 Part 1, # 21 Exhibit 19 Clinoril Label SE 51 Part 2, # 22 Exhibit 19 Clinoril Label SE 51 Part 3, # 23 Exhibit 20 Dettery Robert Combined, # 24 Exhibit 21 Second Supplemental Report of Randall Tackett, Ph.D., # 25 Exhibit 22 Tackett, Ph.D., Randall Vol. 1 2.23.10, # 26 Exhibit 23 P 1st Am Complaint, # 27 Exhibit 24 Bartlett Photos Part 1, # 28 Exhibit 24 Bartlett Photos Part 2, # 29 Exhibit 25 Dep of Bartlett, Greg 2, # 30 Exhibit 26 Dep of Mattson, Jane, # 31 Exhibit 27 Dep of Chodosh, James, # 32 Exhibit 28 Exh 50 Ergin, # 33 Exhibit 28-1, # 34 Exhibit 28-2, # 35 Exhibit 28-3, # 36 Exhibit 28-4, # 37 Exhibit 28-5, # 38 exhibit 28-6, # 39 Exhibit 28-7, # 40 exhibit 28-8, # 41 Exhibit 28-9, # 42 Exhibit 28-11, # 43 Exhibit 28-12, # 44 Exhibit 28-13, # 45 Exhibit 28-14,

		# 46 Exhibit 28-15, # 47 Exhibit 29 1996 Cutaneous Med-Surgery, # 48 Exhibit 30 Bartlett Karen, # 49 Exhibit 31 Deps Werynski Combined, # 50 Exhibit 33 Goldberg, Richard 10.28.09, # 51 Exhibit 34 Pondimin PDR 1996) (Jensen, Keith) (Entered: 04/30/2010)
04/30/2011	169	OBJECTION to 145 MOTION for Summary Judgment *Based on Federal Preemption and Memorandum in Support Thereof* filed by Karen L. Bartlett. (Attachments: # 1 Exhibit (Affidavit) Declaration of Keith M. Jensen, # 2 Exhibit A Pollock Ps Obj's to Dep Testimony, # 3 Exhibit B Morrison Ps Obj's to Dep Testimony, # 4 Exhibit C Sporn Ps Obj's to Dep Testimony, # 5 Exhibit D Dettery Robert Combined, # 6 Exhibit E Publication Label May Differ, # 7 Exhibit F Dr. Charles Hoppes FDA 5.08, # 8 Exhibit G Second Suppl Rep Tackett, # 9 Exhibit H Tackett, Ph.D Randall Vol 1 2.23.10) (Jensen, Keith) (Entered: 04/30/2010)
05/11/2010	172	MEMORANDUM in Support re 146 MOTION for Summary Judgment *(Reply)* filed by Mutual Pharmaceutical Company, Inc., United Research Laboratories, Inc. (Cosgrove, Paul) (Entered: 05/11/2010)

06/01/2010		Minute Entry for proceedings held before Judge Joseph N. Laplante. MOTION HEARING held on 6/1/2010 re 131 MOTION for Summary Judgment, 146 MOTION for Summary Judgment, 145 MOTION for Summary Judgment *Based on Federal Preemption*. Order to issue. (Court Reporter: Susan Bateman/AM; Diane Churas/PM) (Pltfs Atty: Keith Jensen, Eric Roberson, Christine Craig) (Defts Atty: Stephen Judge, Paul Cosgrove, Joseph Thomas) (Total Hearing Time: 4 hours 5 minutes) (dae) Modified on 6/2/2010 to add: Order to issue. (dae). (Entered: 06/02/2010)
06/08/2010		ENDORSED ORDER taking under advisement 146 Motion for Summary Judgment. *Text of Order: On or before June 15, 2010, the parties shall brief the issue (15 page limit, not including exhibits or attachments) of proximate causation with respect to the plaintiff's still-pending "non-failure-to-warn" design defect claims, see Bartlett v. Mutual Pharmaceutical Co., Inc., 659 F. Supp. 2d 279, 291-92 (D.N.H. 2009), and specifically the issue of proximate causation with respect to the plaintiff's claim that the product was "defectively designed or manufactured,...not fit for its intended use, and without using due*

		care in designing or testing it" such that the standard of care required the defendant "to refrain from distributing it at all." See id. So Ordered by Judge Joseph N. Laplante. (Laplante, Joseph) (Entered: 06/08/2010)
06/15/2010	228	Memorandum Per Court's June 8, 2019, Directive for Additional Briefing by Mutual Pharmaceutical Company, Inc. (Cosgrove, Paul) (Entered: 06/15/2010)
06/15/2010	229	NOTICE of Plaintiff's Brief Demonstrating That The Jury Need Not Conclude or Deliberate on Product Withdrawal To Return A Verdict For Strict Product Liability-Design Defect by Karen L. Bartlett. (Attachments: # 1 Exhibit A NH Pattern Jury Instructions) (Jensen, Keith) (Entered: 06/15/2010)
07/06/2010	238	NOTICE of Amended Reply Brief (Doc 235) by Karen L. Bartlett. (Roberson, Eric) (Entered: 07/06/2010)
07/07/2010	239	SURREPLY to Reply to 146 MOTION For Summary Judgment *Per Court's June 8, 2010, Order for Supplemental Briefing on Proximate Causation* filed by Mutual Pharmaceutical Company, Inc. (Cosgrove, Paul) (Entered: 07/07/2010)

07/12/2010	243	ORDER granting in part and denying in part 146 Motion for Summary Judgment filed by Mutual Pharmaceutical, Inc.; denying 145 Motion for Summary Judgment Based on Federal Preemption filed by Mutual Pharmaceutical, Inc.; and granting in part and denying in part 131 Motion for Summary Judgment filed by Karen L. Bartlett. Mutual's motion for summary judgment is GRANTED as to Bartlett's claims of strict products liability (Count 1) and negligence (Count 6) based on failure to warn, as well as her claim of fraud (Count 3), but is DENIED as to her claims of strict products liability (Count 2) and negligence (Count 6) basd on defective deign, as well as her request for enhanced compensatory damages. Mutual's separate motion for summary judgment based on federal pre-emption ruling, is also DENIED. Bartlett's motion for partial summary judgment is GRANTED as to Mutual's set-off and spoliation defenses, but is otherwise DENIED. So Ordered by Judge Joseph N. Laplante. (jb) (Entered: 07/12/2010)
07/20/2010	263	MOTION for Reconsideration re 243 Order on Motion for Summary Judgment, filed by Mutual Pharmaceutical Company, Inc. Follow up on Objection on 8/6/2010.

		(Cosgrove, Paul) (Entered: 07/20/2010)
07/30/2010	284	ORDER denying 263 Motion for Reconsideration re: 243 Order on Motion for Summary Judgment. So Ordered by Judge Joseph N. Laplante. (jb) (Entered: 07/30/2010)
08/02/2010	293	MOTION for Reconsideration re 284 Order on Motion for Reconsideration *of Court's Order Denying Mutual's Motion for Summary Judgment on Plaintiff's Design Defect Claim* filed by Mutual Pharmaceutical Company, Inc. Follow up on Objection on 8/19/2010. (Cosgrove, Paul) (Entered: 08/02/2010)
08/09/2010	303	BRIEF/MEMORANDUM *Regarding Plaintiff's Negligence Claims Pursuant to July 27, 2010, Order* by Mutual Pharmaceutical Company, Inc. (Attachments: # 1 Exhibit Exhibit 1, # 2 Exhibit Exhibit 2) (Cosgrove, Paul) (Entered: 08/09/2010)
08/09/2010	305	RESPONSE re 281 Order, *Brief on Negligence Causation, Enhanced Compensatory Damages, and the Relevance of Warning Evidence (Exhibits Filed Separately)* filed by Karen L. Bartlett. (Roberson, Eric) (Entered: 08/09/2010)

08/11/2010	329	SUMMARY ORDER: Mutual is granted judgment as a matter of law on Bartlett's claims for negligence and enhanced compensatory damages and Bartlett is granted judgment as a matter of law on Mutual's defenses based on the conduct of Bartlett and Dr. Ergin (specifically, the defenses of comparative negligence, apportionment, plaintiffs misconduct/failure to follow instructions, and superseding cause). So Ordered by Judge Joseph N. Laplante. (dae) (Entered: 08/11/2010)
08/11/2010	332	NOTICE of Withdrawal of Defenses by Mutual Pharmaceutical Company, Inc. (Cosgrove, Paul) (Entered: 08/11/2010)
09/08/2010	381	JURY VERDICT. (cmp) (Entered: 09/10/2010)
09/10/2010	386	MOTION for Judgment on the Verdict filed by Karen L. Bartlett. Follow up on Objection on 9/27/2010. (Attachments: # 1 Memorandum of Law, # 2 Proposed Order Exhibit "A" to Memorandum) (Roberson, Eric) (Entered: 09/10/2010)
09/17/2010	388	OBJECTION to 386 MOTION for Judgment on the Verdict filed by Mutual Pharmaceutical Company, Inc. (Judge, Stephen) (Entered: 09/17/2010)

09/20/2010	389	JUDGMENT is hereby entered in accordance with the following: 24 Pretrial Order dismissing claims, Endorsed Order on Motion to Dismiss Gregory Bartlett, Endorsed Order on Motion to Dismiss claims against United Research Laboratories and Claims for Breach of Express and Implied Warrant Against Mutual Pharmaceutical Company, Inc., 243 Order on Motion for Summary Judgment, 284 Order on Motion for Reconsideration, 329 Order, 336 Order on Motion for Reconsideration, 340 Order, 381 Jury Verdict, 387 Order, plus pre-judgment interest pursuant to NH Rev Stat as outlined and post-judgment interest thereon pursuant to 28 USC 1961. Signed by Chief Deputy Clerk Daniel J. Lynch, Approved by US District Judge Joseph N. Laplante. *(Case Closed)* (dae) (Entered: 09/20/2010)
09/20/2010	390	REPLY to Objection to Motion re 386 MOTION for Judgment on the Verdict *as to Remaining Items Related to the Application for Writ of Execution* filed by Karen L. Bartlett. (Roberson, Eric) (Entered: 09/20/2010)
09/24/2010	391	Emergency MOTION to Stay *Any Proceedings to Enforce Judgment Pending Post-Trial Motions and*

		Appeal filed by Mutual Pharmaceutical Company, Inc. Follow up on Objection on 10/12/2010. (Cosgrove, Paul) (Entered: 09/24/2010)
10/01/2010	392	OBJECTION to 391 Emergency MOTION to Stay *Any Proceedings to Enforce Judgment Pending Post-Trial Motions and Appeal* filed Karen L. Bartlett. (Roberson, Eric) (Entered: 10/01/2010)
10/01/2010	393	ORDER temporary granting on an interim basis 391 Motion to Stay Execution of this Court's Judgment. On or before 10/8/10 Mutual to show cause in writing for a further extension of the stay. So Ordered by Judge Joseph N. Laplante. (dae) (Entered: 10/01/2010)
10/04/2010	394	MOTION for New Trial filed by Mutual Pharmaceutical Company, Inc. Follow up on Objection on 10/21/2010. Attachments: # 1 Exhibit Ex. A) (Cosgrove, Paul) (Entered: 10/04/2010)
10/04/2010	395	MOTION for Judgment as a Matter of Law filed by Mutual Pharmaceutical Company, Inc. Follow up on Objection on 10/21/2010. (Attachments: # 1 Exhibit Ex. A Vautour Order, # 2 Exhibit Ex. B FDA Clinical Impact Doc., # 3 Exhibit Ex. C Mutual's Proposed Jury Instructions)

		(Cosgrove, Paul) (Entered: 10/04/2010)
10/05/2010	397	Exhibit A: *Vautour Order* to 395 MOTION for Judgment as a Matter of Law by Mutual Pharmaceutical Company, Inc. (Cosgrove, Paul) (Entered: 10/05/2010)
10/05/2010	398	AMENDED DOCUMENT by Mutual Pharmaceutical Company, Inc., Amendment to 396 Affidavit/ *Declaration of Joseph P. Thomas for Post-Trial Motions (Docs. 394, 395)* (Cosgrove, Paul) Modified on 10/5/2010 to add relationship to Docs. 394 and 395. (dae). (Entered: 10/05/2010)
10/20/2010	402	NOTICE OF APPEAL by Mutual Pharmaceutical Company, Inc. (Filing fee $455, receipt number 0102-673976.) [NOTICE TO COUNSEL: A Transcript Report/Order Form, which can be downloaded from the Forms & Notices section of the First Circuit website at www.ca1.uscourts.gov, MUST be completed and submitted to the U.S. Court of Appeals for the First Circuit.] NOTICE TO COUNSEL: Counsel should register for a First Circuit CM/ECF Appellate Filer Account at http://pacer.psc.uscourts.gov/cmecf/. Counsel should also review the First Circuit requirements for electronic

		filing by visiting the CM/ECF Information section at **Error! Hyperlink reference not valid.** Designation of Exhibits Deadline set for 11/22/2010. (Cosgrove, Paul) (Entered: 10/20/2010)
10/21/2010	405	OBJECTION to 395 MOTION for Judgment as a Matter of Law filed by Karen L. Bartlett. (Attachments: # 1 Appendix A Limited List of Reliance Documents) (Roberson, Eric) (Entered: 10/21/2010)
10/22/2010	406	ORDER granting 391 Motion to Stay; granting 399 Motion to Stay Any Proceedings to Enforce Judgment Pending Post-Trial Motions and Appeal. The execution of this court's judgment and any proceedings to enforce it are STAYED pending the disposition of Mutual's post-trial motions and any subsequent appeal. Mutual shall notify this court and Bartlett immediately if any representations upon which the stay is based (including but not limited to any representations about the financial strength of Mutual's insurers) becomes incorrect or incomplete. So Ordered by Judge Joseph N. Laplante. (jb) (Entered: 10/22/2010)
10/25/2010	409	OBJECTION to 394 MOTION for New Trial filed by Karen L. Bartlett. (Attachments: # 1 Exhibit

		(Affidavit) Declaration of Eric Roberson) (Roberson, Eric) (Additional attachment(s) added on 10/26/2010: # 2 /s/ signed affidavit) (dae). (Entered: 10/25/2010)
10/27/2010	410	Appeal Cover Sheet as to 402 Notice of Appeal filed by Mutual Pharmaceutical Company, Inc. (dae) (Entered: 10/27/2010)
10/28/2010	412	Clerk's Certificate transmitting abbreviated Record on Appeal to US Court of Appeals, documents: 85, 125, Orders of 3/5/10, 243, 251, 269, 271, 272, 275, 278, 281, 284, 290, 320, 321, 329, 335, 336, 340, Orders of 8/16/10, 352, Orders of 8/17/10, 354, Order of 8/23/10, Order of 8/24/10, 366, Orders of 8/26/10, Orders of 8/31/10, Order of 9/2/10, 381, 389, 402, 410, 412 re 402 Notice of Appeal. (dae) (Entered: 10/28/2010)
11/08/2010	414	REPLY to Objection to Motion re 395 MOTION for Judgment as a Matter of Law filed by Mutual Pharmaceutical Company, Inc. (Attachments: # 1 Exhibit Ex. A: FDA AERs Caveats, # 2 Exhibit Ex. B: FDA Postmarketing Drug Safety Evaluations, # 3 Exhibit Ex. C: US Mensing Brief) (Cosgrove, Paul) Modified on 11/23/2010 to add: See Amended Exhibit B at Doc. 421. (dae). (Entered: 11/08/2010)

11/12/2010	418	REPLY to Objection to Motion re 394 MOTION for New Trial filed by Mutual Pharmaceutical Company, Inc. (Attachments: # 1 Exhibit (Affidavit) Ex. A: Affidavit of Hahn) (Cosgrove, Paul) (Entered: 11/12/2010)
11/23/2010	421	AMENDED DOCUMENT by Mutual Pharmaceutical Company, Inc. Amendment to 414 Reply to Objection to Motion, *Exhibit B Postmarketing Drug Safety Evaluations* (Cosgrove, Paul) (Entered: 11/23/2010)
11/29/2010	424	Clerk's Supplemental Certificate transmitted to US Court of Appeals re 402 Notice of Appeal with documents numbered 422. (dae) (Entered: 11/29/2010)
12/16/2010	427	SURREPLY to Reply to 395 MOTION for Judgment as a Matter of Law filed by Karen L. Bartlett. (Roberson, Eric) (Entered: 12/16/2010)
12/17/2010	428	NOTICE of U.S. Supreme Court's grant of writs of certiorari *in Mensing and Demahy* by Mutual Pharmaceutical Company, Inc. (Attachments: # 1 Exhibit - Supreme Court Order List) (Maichl, Linda) (Entered 12/17/2010)
01/05/2011	442	ORDER denying 394 Motion for New Trial; denying 395 Motion for

		Judgment as a Matter of Law. So Ordered by Judge Joseph N. Laplante. (jb) (Entered: 01/05/2011)
01/26/2011	463	Amended NOTICE OF APPEAL, as to 272 Order, Order, 320 Order on Motion to Bifurcate, Order on Motion for Miscellaneous Relief, 284 Order on Motion for Reconsideration, 290 Order on Motion in Limine, 321 Order, 442 Order on Motion for New Trial, Order on Motion for Judgment as a Matter of Law, Order on Motion for Mistrial, Order on Motion to Exclude, 336 Order on Motion for Reconsideration, 354 Order, 275 Order on Motion for Miscellaneous Relief, Order on Motion to Clarify, Order on Motion for Miscellaneous Relief, 271 Order on Motion to Exclude, 352 Order, 389 Judgment, 366 Order, 278 Order, Order on Motion for Miscellaneous Relief, 125 Order, Order, Order on Motion for Miscellaneous Relief, 335 Order on Motion in Limine, 329 Order, Order on Motion in Limine, 281 Order, 269 Order on Motion to Exclude, 340 Order, 85 Order on Motion to Dismiss, 251 Order on Motion to Strike, 243 Order on Motion for Summary Judgment, Order on Motion for Miscellaneous Relief by Mutual Pharmaceutical Company, Inc., amended adding Doc. 442 to the

		Notice of Appeal. Designation of Exhibits Deadline set for 2/28/2011. (Maichl, Linda) (Entered: 01/26/2011)
01/27/2011	464	Clerk's Supplemental Certificate transmitted to US Court of Appeals re 402 Notice of Appeal, 463 Amended Notice of Appeal with documents numbered 463, 4664. (dae) (Entered: 01/27/2011)
02/09/2011	468	NOTICE OF CROSS APPEAL by Karen L. Bartlett. (Filing fee $455, receipt number 0102-709996.) [NOTICE TO COUNSEL: A Transcript Report/Order Form, which can be downloaded from the Forms & Notices section of the First Circuit website at www.ca1.uscourts.gov, MUST be completed and submitted to the U.S. Court of Appeals for the First Circuit.] Designation of exhibits Deadline set for 3/14/2011. (Roberson, Eric) (Entered: 02/09/2011)
02/17/2011	469	Appeal Cover Sheet as to 468 Notice of Cross Appeal, filed by Karen L. Bartlett (dae) (Entered 02/17/2011)
02/17/2011	470	Clerk's Certificate transmitting Record on Appeal to US Court of Appeals, documents numbered 243, 329, Endorsed Order 9/2/10, 387, 469, re 468 Notice of Cross Appeal. A copy of the Notice of Appeal

		mailed to all parties this date. (dae) (Entered: 02/17/2011)
03/15/2011	471	Clerk's Supplemental Certificate transmitted to US Court of Appeals re 468 Notice of Cross Appeal with document: Notice No Exhibit Designation Filed. (dae) (Entered: 03/15/2011)
04/13/2011	472	ORDER of USCA as to 468 Notice of Cross Appeal, filed by Karen L. Bartlett. Motion to Dismiss is granted, and the cross-appeal, No. 11-1178, is dismissed. (ko) (Entered: 04/13/2011)
04/13/2011	473	USCA JUDGMENT as to 468 Notice of Cross Appeal, filed by Karen L. Bartlett. Case dismissed. (ko) (Entered: 04/13/2011)
05/03/2012	488	ORDER/OPINION of USCA as to 402 Notice of Appeal filed by Mutual Pharmaceutical Company, Inc. Affirmed. (dae) (Entered: 05/03/2012)
05/03/2012	489	USCA JUDGMENT as to 402 Notice of Appeal filed by Mutual Pharmaceutical Company, Inc. Judgment of the district court is affirmed. (dae) (Entered: 05/03/2012)

Fifth Circuit Court of Appeals
Court of Appeals Docket #10-2277

Bartlett v. Mutual Pharmaceutical Company, Inc.,

11/04/2010	Civil Case docketed. Notice of appeal (doc. #402) filed by Appellant Mutual Pharmaceutical Company Inc. Docketing Statement due 11/18/2010. Transcript Report/Order form due 11/18/2010. Appearance form due 11/18/2010. [10-2277] (AH)
01/28/2011	AMENDED notice of appeal (doc. #463) filed by Appellant Mutual Pharmaceutical Company Inc. on 01/26/2011. [10-2277] (LB)
02/24/2011	ORDER The parties have filed cross-appeals in Civil No. 08-00358-JL (D. N.H.). Pursuant to Fed. R. App. P. 28.1, it is hereby ordered that defendant Mutual Pharmaceutical Company Inc. be deemed the appellee/cross-appellant ("appellee"). The parties are directed to use the above caption on all future filings related to these cases. The briefing schedule previously set in Appeal No. 10-2277 is hereby vacated. A new briefing schedule will be set once the record on appeal, including all necessary transcripts, is complete. The attached information sheet sets forth the filing requirements for briefs filed pursuant to Fed. R. App. P. 28.1. Any party wishing to object to any part of this order must file a written objection to no later than March 10, 2011. [10-2277, 11-1178] (LB)

03/14/2011	MOTION to dismiss case filed by Appellant/Cross-Appellee Mutual Pharmaceutical Company Inc. in 11-1178. Certificate of service dated 03/14/2011. [10-2277, 11-1178] (LEM)
03/14/2011	RESPONSE filed by Appellee/Cross Appellant Karen L. Bartlett in 10-2277, 11-1178 to motion to stay [5532807-2]. Certificate of service dated 03/14/2011. [10-2277, 11-1178]-[Edited 03/15/2011 by LB] CLERK'S NOTE: Docket entry was edited to modify the docket text. [10-2277, 11-1178] (CMC)
03/17/2011	REPLY filed by Appellant/Cross-Appellee Mutual Pharmaceutical Company, Inc. in 10-2277, 11-1178 to motion to stay [5533332-2], motion to stay [5532807-2]. Certificate of service dated 03/17/2011. [10-2277, 11-1178] (LEM)
04/12/2011	ORDER entered by Sandra L. Lynch, Chief Appellate Judge; Kermit V. Lipez, Appellate Judge and Jeffrey R. Howard, Appellate Judge granting motion to dismiss case and the cross-appeal No. 11-1178 is dismissed [10-2277, 11-1178] (LB)
08/09/2011	APPELLANT'S BRIEF filed by Appellant Mutual Pharmaceutical Company, Inc. Certificate of service dated 08/08/2011. Nine paper copies identical to that of the electronically filed brief must be submitted so that they are received by the court on or before 08/16/2011. [10-

2277] (BLC)

08/10/2011 APPENDIX filed by Appellant Mutual Pharmaceutical Company Inc. Number of volumes: 7. Number of copies: 5. Certificate of service dated 08/08/2011. [10-2277] (BLC)

10/07/2011 BRIEF tendered by Appellee Karen L. Bartlett. Certificate of service dated 10/07/2011. [10-2277] (ENR)

10/11/2011 PLEADING tendered: Supplemental Appendix (6 volumes, 5 copies) filed by Appellee Karen L Bartlett. Certificate of service was not included. [10-2277] (BLC)

10/26/2011 CASE calendared: Wednesday, 12/07/2011 Boston, MA Panel Courtroom. Designation form due 11/09/2011. [10-2277] (LM)

11/02/2011 REPLY BRIEF filed by Appellant Mutual Pharmaceutical Company, Inc. Certificate of service dated 11/01/2011. Nine paper copies identical to that of the electronically filed brief must be submitted so that they are received by the court on or before 11/09/2011. [10-2277] (BLC)

12/07/2011 CASE argued. Panel: Michael Boudin, Appellate Judge; Norman H. Stahl, Appellate Judge and Rogeriee Thompson, Appellate Judge. Arguing attorneys: Joseph Paul Thomas for Mutual Pharmaceutical Company, Inc. and Brooks Pharmacy and United Research Laboratories, Inc. and Keith M. Jensen

for Karen L. Bartlett and Gregory S. Bartlett. [10-2277] (LM)

05/02/2012 OPINION issued by Michael Boudin, Appellate Judge; Norman H. Stahl, Appellate Judge and Rogeriee Thompson, Appellate Judge. Published. [10-2277] (LB)

05/02/2012 JUDGMENT entered by Michael Boudin, Appellate Judge; Norman H. Stahl, Appellate Judge and Rogeriee Thompson, Appellate Judge. 10-2277 Affirmed. [10-2277] (LB)

05/09/2012 ERRATA to opinion (published) [5638037-2] filed. [10-2277] (SBT)

05/16/2012 MOTION to stay *the Mandate* filed by Appellant Mutual Pharmaceutical Company, Inc. Certificate of service dated 05/16/2012 [10-2277] (LEM)

07/06/2012 ORDER entered by Michael Boudin, Appellate Judge; Norman H. Stahl, Appellate Judge and Rogeriee Thompson, Appellate Judge Upon consideration of defendant-appellant Mutual Pharmaceutical Company, Inc.'s motion to stay the mandate, the motion is granted. The issuance of the mandate is hereby stayed for 90 days and if within that period a timely petition for certiorari is filed, the stay of mandate shall continue until final disposition by the United States Supreme Court. If the petition for certiorari is denied, mandate shall issue forthwith. Counsel for

	Mutual Pharmaceutical Company, Inc. is directed to promptly notify the Clerk of this court both of the filing of any such petition for certiorari and the disposition. [10-2277] (LB)
08/01/2012	NOTICE of *Filing Petition for Writ of Certiorari* filed by Appellant Mutual Pharmaceutical Company Inc. Certificate of service dated 08/01/2012. [10-2277] (LEM)
08/06/2012	U.S. SUPREME COURT NOTICE advising a petition for a writ of certiorari was filed on 07/31/2012 and assigned case number 12-142. [10-2277] (LB)
12/03/2012	U.S. SUPREME COURT ORDER entered on 11/30/2012. The petition for a writ of certiorari was granted. [10-2277] (LB)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

KAREN L. BARTLETT
and GREGORY S. BARLETT,

Plaintiffs,

vs. **CASE NO:**

MUTUAL PHARMACEUTICAL COMPANY, INC., UNITED RESEARCH LABORATORIES, INC., and BROOKS PHARMACY,

Defendants.

DEFENDANTS' NOTICE OF REMOVAL

Defendants Mutual Pharmaceutical Company, Inc. ("Mutual"), and United Research Laboratories, Inc., n/k/a URL Pharma, Inc. ("United")(collectively "Defendants"), file this Notice of Removal from the Rockingham County Superior Court, New Hampshire, Docket No.: 08-C-33, to this Court, pursuant to 28 U.S.C. §§ 1332 and 1441, *et seq.* Defendant Maxi-Drug North, Inc. (improperly identified in Plaintiffs' Complaint as Brooks Pharmacy) ("Maxi-Drug North"), consents to this removal (see Exhibit A).

I. PROCEDURAL HISTORY

Defendants hereby remove this case, Case No. 08-C-33, from the Rockingham County Superior Court, New Hampshire, to this Court, pursuant to 28 U.S.C. §§ 1331, 1332 and 1441, *et seq.*

Plaintiffs Karen L. Bartlett and Gregory S. Bartlett filed their Complaint on January 8, 2008, seeking

damages for alleged strict liability – failure to warn (First Claim for Relief); strict liability – design and manufacturing defect (Second Claim for Relief); fraud (Third Claim for Relief); breach of implied warranty (Fourth Claim for Relief); breach of express warranty (Fifth Claim for Relief); negligence (Sixth Claim for Relief); gross negligence (Seventh Claim for Relief); damages; and punitive damages.

Plaintiff's Complaint and a summons were served on Mutual, United, and Maxi- Drug North, on or about January 29, 2008, thereby commencing the action against those defendants.

Defendants Mutual and United filed their Special Plea and Brief Statement of Defense on February 28, 2008.

Defendant Maxi-Drug North filed its Special Plea and Brief Statement of Defense on March 3, 2008.

Pursuant to 28 U.S.C. §§ 1446(a), true and accurate copies of all process, pleadings, and orders served upon Defendants, and a certified copy of the state court record, are attached as Exhibit B. As discussed *infra*, the time period during which Defendants are required by 28 U.S.C. § 1446(b) to file this notice of removal has not expired.

II. REMOVAL JURISDICTION IS PROPER

Removal of this case to this Court is proper under 28 U.S.C. § 1441 *et seq.* The Rockingham County Superior Court, New Hampshire, is located within the jurisdiction of the United States District Court for the District of New Hampshire. Moreover, all the requirements of diversity jurisdiction are met:

(a) The Court has jurisdiction over this action, pursuant to 28 U.S.C. § 1332, because it is a civil

action between citizens of different states in which the amount in controversy exceeds the sum of $75,000, exclusive of interest and costs.

(b) Plaintiffs Karen L. Bartlett and Gregory S. Bartlett are citizens of the State of New Hampshire.

(c) None of the defendants are citizens of the State of New Hampshire:

i. Defendant Mutual is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania with its principal place of business in Philadelphia, Pennsylvania. Thus, for diversity purposes, Mutual is a citizen of Pennsylvania.

ii. Defendant United is a corporation organized and existing under the laws of the State of Delaware with its principal place of business in Philadelphia, Pennsylvania. Thus, for diversity purposes, United is a citizen of Delaware and Pennsylvania.

iii Defendant Maxi-Drug North is a corporation organized and existing under the law of the State of Delaware with its principal place of business in Camphill, Pennsylvania. Thus, for diversity purposes, Maxi-Drug North is a citizen of Delaware and Pennsylvania.

(d) The amount in controversy exceeds $75,000, exclusive of interest. Although Plaintiffs did not allege a specific amount in controversy in their Complaint, the removing party(ies) may establish that the amount in controversy exceeds $75,000 based on plaintiffs' admissions. *See e.g., Packard v. ASC, Inc.*, 1994 U.S. Dist. LEXIS 16695,*2 (D.N.H. Nov. 1, 1994) citing *Hornton v. Liberty Mutual Ins. Co.*, 367 U.S. 348, 353 (1961); *Lowe v. Sears Holding Corp.*, 2008 U.S. Dist LEXIS 17888, *1 (D.N.H. March 4, 2008) ("Where, as

here, the complaint does not put any number on the plaintiff's claimed damages, this court requires the removing defendant to show by a preponderance of the evidence that the amount in controversy exceeds the jurisdictional minimum.") Accordingly, because the amount in controversy was not apparent from the Complaint, Mutual propounded requests for admission to Plaintiffs concerning the amount in controversy on July 7, 2008. (*See* Complaint and Mutual's First Set of Requests for Admission to Plaintiffs, attached as Exhibits C and D, respectively.) Plaintiffs' responses to Mutual's requests for admission were due on August 7, 2008. To date, Plaintiffs have not responded to Mutual's requests for admission. (*See* Affidavit of John F. Friberg, Esq., attached as Exhibit E.)

Plaintiffs' failure to respond to Mutual's requests for admission means that Mutual's requests are deemed admitted. *See* New Hampshire Court Rule 3.16 ("Each of the matters, of which an admission is requested, shall be deemed admitted unless within thirty days after such delivery the party requested files with the Clerk and delivers a copy thereof by mail or in hand to the party requesting such admission, or his attorney, either a sworn denial thereof or a written objection on the ground of privilege or that it is otherwise improper.") *See also Peaslee v. Koenig*, 122 N.H. 828 (1982); *Smith Cove Ass'n v. Special Bd.*, 116 N.H. 24 (1976) (Requests for admission are admitted unless timely response and objection filed). Consequently, Plaintiffs have admitted that "the amount in controversy, exclusive of interests and costs, exceeds $75,000.00." (*See* Mutual's First Set of Requests for Admission to Plaintiffs No. 1, Exhibit D.)

(e) This Notice of Removal is timely pursuant to 28 U.S.C. § 1446(b). Removal must usually be taken within thirty days after receiving the initial pleadings in the case. *See* 28 U.S.C. § 1446(b). However, the removal statute also permits removal of a case at a later time: within thirty days of receiving an "amended pleading, motion, order or *other paper* from which it may first be ascertained that the case is one which is or has become removable." *Id.* By including this language, Congress ensured that the removal deadlines would be flexible enough to accommodate new developments as the case matured. The District of New Hampshire has recognized that an "other paper" within the meaning of the removal statute includes a document that results from the voluntary act of a plaintiff which gives a defendant notice of changed circumstances that support federal jurisdiction. *See Access Group, Inc. v. Frederico*, 2006 U.S. Dist. LEXIS 72888, *7, citing *Huffman v. Saul Holdings Ltd. Partnership*, 194 F.3d 1072, 1078-79 (10th Cir. 1999) ("[T]he critical question in any case is whether the material, voluntarily produced by the plaintiff, unequivocally establishes federal jurisdiction."); *see also Camden Inds. Co. v. United Brotherhood of Carpenters & Joiners*, 246 F. Supp. 259, 260 (D.N.H. 1965).

Here, Plaintiffs' Complaint made no assertion as to the amount in controversy. (*See* Complaint, Exhibit C.) Mutual propounded requests for admission to Plaintiffs on the specific issue of whether the amount in controversy exceeded $75,000. (*See* Mutual's First Set of Requests for Admission to Plaintiffs, Exhibit D.) Plaintiffs have not responded to those requests, and consequently, those requests are now deemed admitted. Plaintiffs' voluntary act was the failure to

respond to requests for admission establishing that the amount in controversy exceeds $75,000. Defendants filed this Notice of Removal within thirty days of Plaintiffs' deadline to respond to Mutual's requests for admission concerning the amount in controversy, and, therefore, this Notice of Removal is timely.

(f) As required by 28 U.S.C. § 1446(d), written notice of this Notice of Removal is being promptly given to plaintiffs by service of this Notice, and a copy of the Notice of Removal has been filed with the Rockingham County Superior Court, New Hampshire.

Accordingly, Defendants have shown that removal is proper under 28 U.S.C. § 1441 *et seq.*

WHEREFORE, Defendants remove this action from the Rockingham County Superior Court, New Hampshire, to this Honorable Court.

Respectfully submitted,

/s/ John E. Friberg, Sr.
John E. Friberg, Sr., NH Bar No. 858
Marc R. Scheer, NH Bar No. 2266
95 Market Street
Manchester, NH 03101
(603) 669-4140
Attorney for Defendants
Mutual Pharmaceutical Company, Inc., and
United Research Laboratories, Inc., n/k/a
URL Pharma, Inc.

OF COUNSEL:

Joseph P. Thomas
Paul J. Cosgrove

ULMER & BERNE LLP
600 Vine Street, Suite 2800
Cincinnati, Ohio 45202
(513) 698-5000; Fax (513) 698-5001

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the above and foregoing instrument was served upon the following counsel of record *via* and facsimile or ordinary U.S. mail this 29th day of August, 2008.

Keith M. Jensen
JENSEN, BELEW & GONZALEZ, PLLC
1024 N. Main Street
Fort Worth, TX 76164

Leslie C. Nixon
Nixon, Raiche, Vogelman, Barry & Slawsky
77 Central Street
Manchester, NH 03101

Mark W. Shaughnessy
BOYLE, MORRISSEY & CAMPO, P.C.
650 Elm Street, Suite 401
Manchester, NH 03101

/s/ John E. Friberg, Sr.

John E. Friberg, Sr.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

KAREN L. BARTLETT **CASE NO.: _____**
and
GREGORY S. BARLETT, **JUDGE: _____**
Plaintiffs,
vs. **MAGISTRATE _____**

MUTUAL PHARMACEUTICAL COMPANY, INC., UNITED RESEARCH LABORATORIES, INC., and BROOKS PHARMACY,
Defendants.

DEFENDANT MAXI-DRUG NORTH, INC.'S CONSENT TO REMOVAL

Defendant Maxi-Drug North, Inc. (improperly identified in plaintiffs' Complaint as Brooks Pharmacy), with full reservation of any and all rights and defenses, hereby consents to removal of the above-captioned case, which was originally filed in the Superior Court of New Hampshire, Rockingham County, Case No. 08-C-33.

Respectfully submitted,

/s/ Mark W. Shaughnessy
Mark W. Shaughnessy, Esq.
Andrew B. Ranks, Esq.
BOYLE, MORRISSEY & CAMPO, PC
650 Elm Street, Suite 401
Manchester, NH 03101
Telephone: 603-668-6216
Fax: 603-668-6217

Attorneys for Maxi-Drug North, Inc.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the above and foregoing instrument was served upon the following counsel of record *via* and facsimile or ordinary U.S. mail this 29 day of August, 2008.

Keith M. Jensen
JENSEN, BELEW & GONZALEZ, PLLC
1024 N. Main Street
Fort Worth, TX 76164

John E. Friberg, Sr.
WADLEIGH STARR & PETERS LLC
95 Market Street
Manchester, NH 03101

/s/ Mark W. Shaughnessy
Mark W. Shaughnessy, Esq.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW HAMPSHIRE

KAREN L. BARTLETT and GREGORY S. BARTLETT,

vs.

Plaintiffs,

CASE NO: 1:08-cv-358

MUTUAL PHARMACEUTICAL COMPANY, INC., UNITED RESEARCH LABORATORIES, INC., and BROOKS PHARMACY,

Defendants.

ADDENDUM TO NOTICE OF REMOVAL

Defendants Mutual Pharmaceutical Company, Inc. ("Mutual"), and United Research Laboratories, Inc., n/k/a URL Pharma, Inc. ("United")(collectively "Defendants"), file this Addendum to their previously filed Notice of Removal (Pleading #1 in the Court's Docket). This Addendum contains Notice of Removal Exhibits A, B, C, D, and E.

Respectfully submitted,

/s/ John E. Friberg, Sr.

John E. Friberg, Sr., NH Bar No. 858
Marc R. Scheer, NH Bar No. 2266
95 Market Street
Manchester, NH 03101
(603) 669-4140
Attorney for Defendants
Mutual Pharmaceutical Company,

Inc., and United Research Laboratories, Inc., n/k/a URL Pharma, Inc.

OF COUNSEL:

Joseph P. Thomas
Paul J. Cosgrove
ULMER & BERNE LLP
600 Vine Street, Suite 2800
Cincinnati, Ohio 45202
(513) 698-5000; Fax (513) 698-5001

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing instrument was served upon the following counsel of record *via* U.S. mail this 5th day of September, 2008.

Keith M. Jensen
JENSEN, BELEW & GONZALEZ, PLLC
1024 N. Main Street
Fort Worth, TX 76164

Leslie C. Nixon
Nixon, Raiche, Vogelman, Barry & Slawsky
77 Central Street
Manchester, NH 03101

Mark W. Shaughnessy
BOYLE, MORRISSEY & CAMPO, P.C.
650 Elm Street, Suite 401
Manchester, NH 03101

/s/ John E. Friberg, Sr.
John E. Friberg, Sr.

STATE OF NEW HAMPSHIRE

ROCKINGHAM, SS. SUPERIOR COURT

Docket No. 08-C-33

KAREN L. BARTLETT and

GREGORY S. BARLETT,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,
UNITED RESEARCH LABORATORIES, INC., AND BROOKS PHARMACY,

DEFENDANTS' NOTICE OF REMOVAL

Notice is hereby given that on the 29th day of August, 2008, defendants Mutual Pharmaceutical Company, Inc., and United Research Laboratories, Inc., n/k/a URL Pharma, Inc. ("United"), duly filed in the United States District Court for the District of New Hampshire, a notice of removal of this action to such court from the Rockingham County Superior Court, New Hampshire, Docket No.: 08-C-33, pursuant to 28 U.S.C. §§ 1332 and 1441, and thereby removed this action to the federal court. Pursuant to 28 U.S.C. §1446(d), this state action shall proceed no further.

Respectfully submitted,

/s/ John E. Friberg, Sr.

John E. Friberg, Sr., NH Bar No. 858
95 Market Street
Manchester, NH 03101
(603) 669-4140

Attorney for Defendants
Mutual Pharmaceutical Company, Inc., and
United Research Laboratories, Inc., n/k/a
URL Pharma, Inc.

THE STATE OF NEW HAMPSHIRE

ROCKINGHAM, SS. SUPERIOR COURT

DOCKET NO. 08-C-33

Karen L. Bartlett and Gregory S. Bartlett

v.

Mutual Pharmaceutical Co., Inc., United Research Laboratories, Inc., and Brooks Pharmacy

SPECIAL PLEA AND BRIEF STATEMENT OF DEFENSE

NOW COMES the defendant, Mutual Pharmaceutical Co., Inc. (hereinafter "MPCI"), and United Research Laboratories, Inc. (hereinafter "URL"), by and through their attorneys, Wadleigh, Starr & Peters, P.L.L.C., and by way of special plea and brief statement of defense say as follows:

1. The Plaintiffs' Writ and attached Complaint, and each statement of claims therein fail to state a claim against MPCI upon which relief may be granted.

2. The Plaintiffs' Writ and attached Complaint, and each statement of claims therein fail to state a claim against URL upon which relief may be granted.

3. Defendant URL did not manufacture or distribute the Sulindac involved in this case and therefore should be dismissed as a defendant.

4. In the absence of proof by the Plaintiffs that the product used by Mrs. Bartlett was made or distributed by URL, URL may not be

held liable for any of the plaintiffs' claims and should be dismissed.

5. The defendants, MPCI and URL, generally and specifically deny all claims of liability set forth in the Complaint, including but not limited to negligence, breach of warranty, and strict product liability.

6. Defendants, MPCI and URL, deny that Sulindac was defective or unreasonably dangerous as alleged.

7. The Plaintiffs' claims are barred by the doctrine(s) contained in Restatement (Second) of Torts § 402A, Comment k, and Restatement (Third) of Torts: Product Liability § 6.

8. The Plaintiffs' claims are barred, in whole or in part, by misuse or unintended use of the prescription drug of Sulindac.

9. The Plaintiffs' claims are barred, in whole or in part, by the "Learned Intermediary" or "Informed Intermediary" doctrine.

10. All claims alleging failure to warn should be dismissed as a matter of law under the Learned Intermediary or Informed Intermediary Doctrine.

11. Comparative negligence is reserved as a defense pending further discovery.

12. Independent, intervening and superceding causes operate as a defense.

13. No proximate causation exists.

14. No medical causation exists.

15. The Plaintiffs' claims may be barred, in whole or in part, because the Plaintiffs assumed the risks disclosed concerning Sulindac, and waived and are estopped from asserting any claim arising from the manifestation of such risks.

16. The Plaintiffs' claims are barred, in whole or in part, because any injuries or damages allegedly sustained were caused by a pre-existing or unrelated medical condition, disease, or illness suffered by Mrs. Bartlett.

17. Based upon the state of scientific skill and knowledge at the time Sulindac was distributed, it was reasonably safe and its benefits exceeded any risk associated with its use.

18. The Plaintiffs' claims are barred, in whole or in part, because adequate warnings were given of all known or reasonably knowable risks associated with the use of Sulindac.

19. The Plaintiffs' claims are barred, in whole or in part, because Sulindac is comprehensively regulated by the United States Food & Drug Administration (hereinafter "FDA") pursuant to the Federal Food, Drug & Cosmetic Act (hereinafter "FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated thereunder, and the plaintiffs' claims conflict with the FDCA, with the regulations promulgated by the FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations and with the specific determinations by the FDA specifying the language that should be used in

the labeling accompanying Sulindac. Accordingly, the Plaintiffs' claims are pre-empted by the Supremacy Clause of the United States Constitution, Article VI, Clause 2 in the laws of the United States.

20. The Plaintiffs' claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by the FDA under the FDCA.

21. All claims for breach of common law duties under State law, including failure to warn, are preempted by Federal law and compliance with Federal law and applicable Federal regulations. Accordingly, said common law State claims should be dismissed.

22. The Plaintiffs' claims may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of MCPI and URL and all of its activities with respect to the subject product Sulindac have been and are conducted under the supervision of the FDA.

23. The Plaintiffs' strict liability claims cannot be maintained against a prescription drug manufacturer under the facts of this case.

24. The Plaintiffs' claims are governed, in whole or in part, by Sections 2 and 4 of the Restatement (Third) of Torts (including the comments thereto) because MCPI and URL complied with all applicable statutes and with the requirements and regulations of the FDA.

25. All claims of fraud, and misrepresentation are denied.

26. The Plaintiffs' claims of fraud are barred by their failure to justifiably and reasonably rely on any alleged misrepresentation of MCPI or URL.

27. The Plaintiffs' claims of fraud are barred because any alleged misrepresentation on which the Plaintiffs relied did not constitute misrepresentations of material facts.

28. Defendants, MPCI and URL, deny that exemplary or punitive damages are allowed under New Hampshire law as a matter of fact or law.

29. Defendants, MPCI and URL, deny any alleged wanton, or willful conduct, or conscious disregard for safety as a matter of fact or law in New Hampshire.

30. The Plaintiffs' claims are barred, in whole or in part, by their failure to heed warnings and failure to follow instructions.

31. The Plaintiffs' claims are barred, in whole or in part, by disclaimer and by the Plaintiffs' failure to give notice of the breach of the warranty within a reasonable time after accepting tender.

32. The Plaintiffs' claims are barred because MCPI's and URL's conduct is not the producing cause, proximate cause, or a cause in fact of the plaintiffs' alleged injuries.

33. The Plaintiffs' claims are barred, in whole or in part, because any alleged defect was not known or scientifically knowable at the time the product was distributed.

34. The Plaintiffs' claims are barred, in whole or in part, by the doctrine of Informed Consent. The Plaintiff was informed of the risks associated with the treatment and willingly consented to the treatment despite those risks.

35. Defendants reserve the right to raise alteration and substantial change of the product, including the package insert warnings accompanying the product, by Brooks Pharmacy which dispensed the prescription to the plaintiff.

36. Defendants reserve the right to claim and prove that non-parties to this litigation are responsible in whole or in part for the claims and injuries alleged by the plaintiff, and to request that the jury allocate proportionate fault to these non-parties under New Hampshire law.

37. MCPI and URL reserve the right to add to this Special Plea and Brief Statement of Defense pending further discovery.

Respectfully submitted,

/s/ John E. Friberg, Sr.

John E. Friberg, Sr.,
NH Bar No. 858
95 Market Street
Manchester, NH 03101
(603) 669-4140

Attorney for Defendants
Mutual Pharmaceutical Company, Inc.,

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was forwarded this day to Leslie C. Nixon, Esquire, attorney for the plaintiffs, and Michael P. Johnson, Esquire, attorney for Brooks Pharmacy.

/s/ John E. Friberg, Sr.
John E. Friberg, Sr.,

United States District Court
For the District of New Hampshire

KAREN L. BARTLETT
and **CASE NO. 08-cv-358-JL**
GREGORY S. BARTLETT,

Plaintiffs, **Judge Joseph N. Laplante**

vs.

MUTUAL PHARMACEUTICAL COMPANY, INC., UNITED RESEARCH LABORATORIES, INC., and BROOKS PHARMACY,

Defendants.

ANSWER OF MUTUAL PHARMACEUTICAL COMPANY, INC.

Mutual Pharmaceutical Company, Inc. ("Mutual"), answers plaintiffs' Complaint as follows:

Mutual incorporates the following into its response to each paragraph below: Mutual denies each allegation in plaintiffs' Complaint except those expressly admitted. Mutual also states that to the extent that allegations in plaintiffs' Complaint refer generally to "Defendants," Mutual answers said allegations only as to itself. To the extent the allegations in plaintiffs' Complaint refer to defendants or entities other than Mutual, Mutual states that it lacks knowledge or information sufficient to form a belief as to the truth of those allegations.

GENERAL ALLEGATIONS

1. Mutual admits that plaintiffs seek recovery pursuant to various legal theories. Further, Mutual admits that Sulindac is a prescription drug and that upon information and belief Ms. Bartlett is a resident of the County of Rockingham, New Hampshire. Mutual denies the remaining allegations in Paragraph 1 of plaintiffs' Complaint.

2. Mutual admits that it is a Pennsylvania corporation with its principal place of business at 1100 Orthodox Street, Philadelphia, PA 19124. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 2 of plaintiffs' Complaint.

3. Mutual admits that United Research Laboratories, Inc. ("United"), is a Pennsylvania corporation with its principal place of business at 1100 Orthodox Street, Philadelphia, PA 19124. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 3 of plaintiffs' Complaint.

4. Mutual admits that it has engaged in the testing, manufacturing, packaging, and distribution of Sulindac. The allegations in Paragraph 4 of plaintiffs' Complaint regarding alleged "predecessors" constitute purported legal conclusions rather than allegations of fact to which no answer by Mutual is required. To the extent an answer is required, Mutual denies those allegations. Mutual admits that plaintiffs purport to identify Mutual, United, and "their predecessors" collectively as "Defendants" but denies that such characterization is complete or accurate. Mutual denies the remaining allegations in Paragraph 4 of plaintiffs' Complaint.

5. Mutual admits upon information and belief that plaintiffs live in New Hampshire. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 5 of plaintiffs' Complaint.

6. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 of plaintiffs' Complaint.

7. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7 of plaintiffs' Complaint.

8. Mutual admits that Sulindac is a prescription nonsteroidal anti-inflammatory drug ("NSAID"). Mutual lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 8 of plaintiffs' Complaint.

9. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of plaintiffs' Complaint.

10. Mutual denies that Sulindac is a seizure medication. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 10 of plaintiffs' Complaint.

11. The allegations in Paragraph 11 of plaintiffs' Complaint constitute purported legal conclusions rather than allegations of fact to which no answer by Mutual is required. To the extent an answer is required, Mutual denies those allegations. Mutual denies that Paragraph 11 completely or accurately characterizes any federal regulations, SJS, or TENS. Mutual denies all remaining allegations in Paragraph 11.

12. Mutual denies that its conduct caused any harm to plaintiff. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of plaintiffs' Complaint concerning plaintiff's alleged injuries and medical condition, and, accordingly denies those allegations. Mutual denies all remaining allegations in Paragraph 12.

13. Mutual denies the allegations in Paragraph 13 of plaintiffs' Complaint.

14. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14 of plaintiffs' Complaint concerning plaintiff's alleged state of mind and hypothetical conduct. Mutual denies that it owed a duty to plaintiff, breached any duty to plaintiff, or that its product was in any way defective. Answering further, to the extent Mutual owed a duty to any person, such duty was fulfilled. The remaining allegations in Paragraph 14 constitute purported legal conclusions rather than allegations of fact to which no answer by Mutual is required. To the extent an answer is required, Mutual denies those allegations. Mutual denies all other allegations in Paragraph 14.

15. Mutual denies the allegations in Paragraph 15 of plaintiffs' Complaint.

16. Mutual denies the allegations in Paragraph 16 of plaintiffs' Complaint.

17. Mutual denies the allegations in Paragraph 17 of plaintiffs' Complaint.

18. Mutual denies the allegations in Paragraph 18 of plaintiffs' Complaint.

19. Mutual denies the allegations in Paragraph 19 of plaintiffs' Complaint.

20. Mutual denies that its conduct caused any harm to plaintiff. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20 of plaintiffs' Complaint concerning plaintiff's alleged injuries or medical condition. Mutual denies any remaining allegations in Paragraph 20.

21. Mutual denies that its conduct caused any harm to plaintiff. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 21 of plaintiffs' Complaint concerning plaintiff's alleged injuries or medical condition. Mutual denies any remaining allegations in Paragraph 21.

LIABILITY OF GENERIC DRUG MANUFACTURER

22. Mutual admits that Sulindac is a generic drug. Mutual admits that the brand-name version of Sulindac is Clinoril, which was approved by the FDA in September, 1978. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 22 of plaintiffs' Complaint.

23. Mutual admits that an Abbreviated New Drug Application ("ANDA") is filed by a generic drug applicant for approval of a generic drug and that the labeling of a generic drug must be the "same as" the reference listed drug ("RLD"). Mutual admits that it complied with all applicable CFR sections governing drug labeling for Sulindac. Mutual denies that paragraph 23 of plaintiffs' Complaint fully and

accurately set forth the relevant CFR provisions governing the ANDA process. The remaining allegations in Paragraph 23 of plaintiffs' Complaint constitute purported legal conclusions rather than allegations of fact to which no answer by Mutual is required. To the extent an answer is required, Mutual denies those allegations. Mutual denies any remaining allegations in Paragraph 23.

24. The allegations in Paragraph 24 of plaintiffs' Complaint constitute purported legal conclusions rather than allegations of fact to which no answer by Mutual is required. To the extent an answer is required, Mutual denies the allegations. Mutual denies any remaining allegations in Paragraph 24.

25. Mutual admits that plaintiffs have accurately quoted an excerpt of FDA's November 1999 Guidance for Industry: Changes to an Approved NDA or ANDA. Mutual denies that plaintiffs have accurately quoted an excerpt of FDA's November 2004 Guidance for Industry: Changes to an Approved NDA or ANDA. Insofar as the allegations in Paragraph 25 of plaintiffs' Complaint constitute purported legal conclusions rather than allegations of fact, no answer by Mutual is required. To the extent an answer is required, Mutual denies those allegations. Mutual denies any remaining allegations in Paragraph 25.

26. Paragraph 26 of plaintiffs' Complaint states purported conclusions of law to which no response is required. To the extent a response is required, Mutual denies those allegations. Mutual admits only that it complied with all applicable CFR sections with respect to products manufactured under its ANDA for Sulindac. Mutual denies the remaining allegations in Paragraph 26.

CAUSES OF ACTION

FIRST CLAIM FOR RELIEF
STRICT PRODUCT LIABILITY – FAILURE TO WARN

27. Mutual incorporates its responses to Paragraphs 1 through 26 of Plaintiffs' Complaint as if fully set forth herein.

28. Mutual admits only that it has manufactured and distributed Sulindac. The balance of Paragraph 28 states purported conclusions of law to which no response is required or necessary. To the extent a response is required, Mutual denies those allegations. Mutual denies all other allegations in Paragraph 28.

29. Mutual denies the allegations in Paragraph 29 of plaintiffs' Complaint.

30. Mutual denies the allegations in Paragraph 30 of plaintiffs' Complaint.

31. Mutual denies the allegations in Paragraph 31 of plaintiffs' Complaint.

32. Mutual denies the allegations in Paragraph 32 of plaintiffs' Complaint.

33. Mutual admits only that Sulindac is a prescription drug. Mutual denies the remaining allegations in Paragraph 33 of plaintiffs' Complaint.

34. Mutual denies the allegations in Paragraph 34 of plaintiffs' Complaint.

35. Mutual denies the allegations in Paragraph 35 of plaintiffs' Complaint.

SECOND CLAIM FOR RELIEF
STRICT PRODUCT LIABILITY – DEFECTIVE IN DESIGN OR MANUFACTURE

36. Mutual incorporates its responses to Paragraphs 1 through 35 of plaintiffs' Complaint as if fully set forth herein.

37. Mutual admits only that it has manufactured, sold, and distributed Sulindac. Mutual denies the remaining allegations in Paragraph 37 of plaintiffs' Complaint.

38. Mutual is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning whether Sulindac reached consumers without substantial change in condition. Mutual denies the remaining allegations in Paragraph 38 of plaintiffs' Complaint.

39. Mutual denies the allegations in Paragraph 39 of plaintiffs' Complaint.

40. Mutual denies the allegations in Paragraph 40 of plaintiffs' Complaint.

41. Mutual denies the allegations in Paragraph 41 of plaintiffs' Complaint.

42(a)-(e). Mutual denies the allegations in Paragraph 42(a)-(e) of plaintiffs' Complaint.

43. Mutual is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning whether Sulindac reached consumers without substantial change in condition. Mutual denies the remaining allegations in Paragraph 43 of plaintiffs' Complaint.

44. Mutual is without knowledge or information sufficient to form a belief as to the truth of the

allegations concerning the manner in which plaintiff allegedly used Sulindac. Mutual denies the remaining allegations in Paragaraph 44 of plaintiffs' Complaint.

45. Mutual denies the allegations in Paragraph 45 of plaintiffs' Complaint.

46. Mutual denies the allegations in Paragraph 46 of plaintiffs' Complaint.

47. Mutual denies the allegations in Paragraph 47 of plaintiffs' Complaint.

48. Mutual denies the allegations in Paragraph 48 of plaintiffs' Complaint.

THIRD CLAIM FOR RELIEF FRAUD

49. Mutual incorporates its responses to Paragraphs 1 through 48 of plaintiffs' Complaint as if fully set forth herein.

50. Mutual admits only that it has manufactured, sold, and distributed Sulindac. Mutual denies the remaining allegations in Paragraph 50 of plaintiffs' Complaint.

51. Mutual denies the allegations in Paragraph 51 of plaintiffs' Complaint.

52(a)-(d). Mutual denies the allegations in Paragraph 52(a)-(d) of plaintiffs' Complaint.

53. Mutual denies the allegations in Paragraph 53 of plaintiffs' Complaint.

54. Paragraph 54 of plaintiffs' Complaint contains statements of purported legal conclusions rather than allegations of fact regarding duties allegedly imposed upon Mutual by law to which no answer by Mutual is required. To the extent an answer is required, Mutual

denies those allegations. Mutual denies all other allegations in Paragraph 54.

55. Mutual denies the allegations in Paragraph 55 of plaintiffs' Complaint.

56. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 56 of plaintiffs' Complaint concerning plaintiff's alleged state of mind. Mutual denies all other allegations in Paragraph 56.

57. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 57 of plaintiffs' Complaint concerning plaintiff's alleged state of mind. Mutual denies all other allegations in Paragraph 57.

58. Mutual denies the allegations in Paragraph 58 of plaintiffs' Complaint.

59. Mutual denies the allegations in Paragraph 59 of plaintiffs' Complaint.

FOURTH CLAIM FOR RELIEF
BREACH OF IMPLIED WARRANTY

60. Mutual incorporates its responses to Paragraphs 1 through 59 of plaintiffs' Complaint as if fully set forth herein.

61. Mutual admits only that it has manufactured, sold, and distributed Sulindac. Mutual denies the remaining allegations in Paragraph 61 of plaintiffs' Complaint.

62. Paragraph 62 of plaintiffs' Complaint contains statements of purported legal conclusions rather than allegations of fact regarding an alleged implied warranty to which no answer by Mutual is required. To the extent an answer is required, Mutual denies

those allegations. Mutual denies all other allegations in Paragraph 62.

63. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 63 of plaintiffs' Complaint concerning plaintiff's alleged state of mind. Mutual denies all other allegations in Paragraph 63.

64. Mutual is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning the plaintiff's alleged prescribed use of Sulindac. Mutual denies all other allegations in Paragraph 64 of plaintiffs' Complaint.

65. Mutual denies the allegations in Paragraph 65 of plaintiffs' Complaint.

66. Mutual denies the allegations in Paragraph 66 of plaintiffs' Complaint.

67. Mutual denies the allegations in Paragraph 67 of plaintiffs' Complaint.

FIFTH CLAIM FOR RELIEF
BREACH OF EXPRESS WARRANTY

68. Mutual incorporates its responses to Paragraphs 1 through 67 of plaintiffs' Complaint as if fully set forth herein.

69. Mutual denies the allegations in Paragraph 69 of plaintiffs' Complaint.

70. Mutual denies the allegations in Paragraph 70 of plaintiffs' Complaint.

71. Mutual denies the allegations in Paragraph 71 of plaintiffs' Complaint.

SIXTH CLAIM FOR RELIEF
NEGLIGENCE

72. Mutual incorporates its responses to Paragraphs 1 through 71 of Plaintiffs' Complaint as if fully set forth herein.

73. Paragraph 73 of plaintiffs' Complaint states conclusions of law to which no response is required or necessary. To the extent a response is required, Mutual denies the allegations in Paragraph 73.

74. Mutual denies the allegations in Paragraph 74 of plaintiffs' Complaint.

75(a)-(h). Mutual denies the allegations in Paragraph 75(a)-(h) of plaintiffs' Complaint.

76. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 76 of plaintiffs' Complaint concerning plaintiff's alleged state of mind. Mutual denies all other allegations in Paragraph 76 of plaintiffs' Complaint.

77. Mutual denies the allegations in Paragraph 77 of plaintiffs' Complaint.

78. Mutual denies the allegations in Paragraph 78 of plaintiffs' Complaint.

79. Mutual denies the allegations in Paragraph 79 of plaintiffs' Complaint.

80. Mutual denies the allegations in Paragraph 80 of plaintiffs' Complaint.

81. Mutual denies the allegations in Paragraph 81 of plaintiffs' Complaint.

82. Mutual denies the allegations in Paragraph 82 of plaintiffs' Complaint.

SEVENTH CLAIM FOR RELIEF
GROSS NEGLIGENCE

83. Mutual incorporates its responses to Paragraphs 1 through 82 of plaintiffs' Complaint as if fully set forth herein.

84. Paragraph 84 of plaintiffs' Complaint states conclusions of law to which no response is required or necessary. To the extent a response is required, Mutual denies the allegations in Paragraph 84.

85. Mutual denies the allegations in Paragraph 85 of plaintiffs' Complaint.

86(a)-(d). Mutual denies the allegations in Paragraph 86(a)-(d) of plaintiffs' Complaint.

87. Mutual denies the allegations in Paragraph 87 of plaintiffs' Complaint.

88. Mutual denies the allegations in Paragraph 88 of plaintiffs' Complaint.

89. Mutual denies the allegations in Paragraph 89 of plaintiffs' Complaint.

90. Mutual denies the allegations in Paragraph 90 of plaintiffs' Complaint.

91. Mutual denies the allegations in Paragraph 91 of plaintiffs' Complaint.

92. Mutual denies the allegations in Paragraph 92 of plaintiffs' Complaint.

DAMAGES

93(1)-(8). Mutual denies the allegations in Paragraph 93(1)-(8) of plaintiffs' Complaint.

PUNITIVE DAMAGES

93. (improperly numbered 93 in plaintiffs' Complaint). Mutual incorporates its responses to Paragraphs 1 through 93(1)-(8) of plaintiffs' Complaint as if fully set forth herein.

94. Mutual denies the allegations in Paragraph 94 of plaintiffs' Complaint.

PRAYER FOR RELIEF

Mutual admits that plaintiffs seek the relief requested in the corresponding paragraph of the Complaint beginning, "WHEREFORE," including all sub-parts, but denies that plaintiffs are entitled to the relief requested, or any recovery whatsoever.

DEFENSES

Pleading further, Mutual Pharmaceutical Company, Inc. ("Mutual"), asserts the following defenses to plaintiffs' Complaint and reserves its right to amend or supplement these defenses as further information becomes available through discovery:

1. Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

2. Plaintiffs' Complaint should be dismissed for improper venue.

3. Plaintiffs' Complaint should be dismissed becau there is no personal jurisdiction over defendant Mutual.

4. This Court lacks subject matter jurisdiction over plaintiffs' claims.

5. Plaintiffs have failed to join all necessary and appropriate parties.

6. Mutual is not a proper party-defendant.

7. Plaintiffs have failed to plead her claims with sufficient particularity.

8. Plaintiffs lack standing and/or capacity to assert the claims alleged in the Complaint.

9. Plaintiffs' claims are barred by the doctrine of unclean hands, laches, waiver and/or estoppel.

10. Any claim or cause of action that plaintiffs may have had is barred by the applicable statutes of limitation and/or statues of repose.

11. Lack of privity between plaintiffs and Mutual bars any claims based on contractual or warranty theories.

12. The product at issue in this litigation has been formulated, designed, tested, manufactured, processed, distributed, and labeled in accordance with the provisions of the federal Food, Drug and Cosmetic Act and any regulations promulgated thereunder. Therefore, plaintiffs' claims are preempted or barred by federal law and regulation.

13. Plaintiffs' claims are barred because at the time the product at issue in this litigation left Mutual's control, it complied with applicable codes, standards, regulations, and specifications established, adopted, promulgated, or approved by the United States or by New Hampshire law, or by any agency of the United States or New Hampshire. The product was reasonably fit, suitable, and safe for its intended purpose.

14. The product at issue in this litigation was modified, altered, or changed from the condition in which it was sold, which modification, alteration, or change caused or contributed to cause plaintiffs' alleged damages.

15. The product at issue in this litigation conformed precisely in all ways to its specifications and performance standards and posed no danger in its manufacture and composition.

16. Plaintiffs' claims are barred because at the time the product at issue in this litigation left Mutual's control, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which plaintiffs seek to recover damages without substantially impairing the reasonably anticipated or intended function of the product.

17. Plaintiffs' damages, if any, were caused by inherent characteristics of the product that are generic aspects of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability. Further, all reasonable precautions consistent with legal duties and obligations were taken to protect third parties from any dangers posed by the inherent characteristics of the product.

18. The benefits of the product outweigh the risk of danger or harm, if any, inherent in the product.

19. There is no duty to warn about any possible dangers that were not known at the time of manufacture and sale of product in question.

20. Any communications and/or actions between any of the defendants and the United States Food and Drug Administration and/or any governmental agency or entity are constitutionally protected under the Noerr-Pennington Doctrine and the First Amendment to the United States Constitution.

21. The product at issue in this litigation was sold in a reasonable and prudent manner based upon available medical and scientific knowledge and further were processed in accordance with and pursuant to all applicable regulations of the Federal Food and Drug Administration.

22. Based on the state of scientific, medical, and technological knowledge at the time they were marketed, the product at issue in this litigation was reasonably safe for their normal and foreseeable uses. In light of the existing reasonably available medical, scientific, and technological knowledge, the design characteristics, if any, that allegedly caused the damages plaintiff complains of, or the alleged risk of such characteristics, could not have been known.

23. Mutual's actions conformed to the state of the art of reasonably available scientific and technological knowledge at all times relevant to this lawsuit. At the time the product left the control of Mutual, the product was in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, or labeled.

24. Mutual at all times discharged its duty to warn through appropriate and adequate warnings in accordance with federal statutes and regulations consistent with the existing state of medical and scientific knowledge.

25. If plaintiff sustained damages by reason of the matters alleged in the Complaint, which is denied, then said damages were caused solely by or contributed to by the acts or fault of third parties and were not caused or contributed to by any acts or fault

of Mutual, its officers, agents, contractors, servants, employees, or others for whom it was responsible.

26. Plaintiffs' damages, if any, were proximately caused by unforeseeable, independent, intervening, or superseding events beyond the control, and unrelated to the conduct of Mutual. The actions and omissions of Mutual, if any, were superseded by such unforeseeable, independent, intervening, and superseding events.

27. The injuries and damages claimed by plaintiffs resulted from their own conduct so that plaintiffs' claims are barred, in whole or in part, by the comparative negligence, plaintiffs' misconduct, fault, or responsibility of causation attributed to plaintiffs. Thus, plaintiffs' claims should be dismissed, reduced, offset, or barred in accordance with the principles of comparative negligence. Plaintiffs' recovery of damages, if any exist, must be reduced by the comparative negligence and/or fault of plaintiffs and other persons, including responsible non-parties, pursuant to New Hampshire law.

28. The injuries and damages claimed by plaintiffs were caused, in whole or in part, by the acts or omissions of persons other than Mutual, over whom Mutual, had no control. Therefore, any recovery by plaintiffs should be apportioned in direct proportion to such fault in accordance with applicable law.

29. Any injuries or damages sustained by plaintiffs were directly and proximately caused by the failure of plaintiff to heed warnings and instructions. Therefore, no recovery is available to plaintiffs.

30. If plaintiffs sustained damages as alleged in plaintiffs' Complaint, which is denied, plaintiffs failed to mitigate their damages.

31. Plaintiff's misuse of the product, which was not reasonably foreseeable, caused plaintiffs' alleged damages, if any, and plaintiffs' claims therefore may be barred or reduced by applicable law.

32. Plaintiffs' claims are barred to the extent the injuries alleged in the Complaint were caused or enhanced by pre-existing or unrelated medical, genetic, environmental, or psychiatric conditions, diseases or illnesses, by plaintiff's own idiosyncratic reactions, and/or by operation of nature.

33. Plaintiffs' claims are barred on the grounds that plaintiffs knew, or in the exercise of ordinary care should have known, of the risks of the injuries or damages alleged in the Complaint, if any, and nevertheless, did freely and voluntarily assume said risks, and in this undertaking proximately caused and contributed to the losses, injuries, or damage, if any, alleged by plaintiffs.

34. Plaintiffs' claims against Mutual are barred by the learned intermediary doctrine.

35. Plaintiffs are barred, in whole or in part, from recovery due to spoliation of evidence.

36. There is no responsibility for either the acts or omissions of the knowledgeable users or misinformation or lack of information provided to the plaintiffs by others.

37. With respect to each and every cause of action, plaintiffs are not entitled to recover because of the delay and the fundamental unfairness and prejudice due to the excessive delay from the date of the alleged use of the products allegedly sold by Mutual and the filing of the Complaint.

38. There were no warranties, either express or implied, between plaintiffs and Mutual.

39. Mutual breached no warranties, either express or implied, which may have existed between it and plaintiff.

40. Plaintiffs failed to give notice of any alleged breach of any warranty as required by state law and is, therefore, barred from any recovery for such claims.

41. The express and implied warranties alleged to have been made were expressly disclaimed and excluded by the label; any and all statements made concerning the product referred to in the Complaint applied only when used as directed.

42. To the extent plaintiffs seek exemplary or punitive damages, the Complaint fails to allege facts sufficient to entitle plaintiffs to an award of exemplary or punitive damages.

43. To the extent plaintiffs seek exemplary or punitive damages, such damages are prohibited under the Fifth, Eighth, and Fourteenth Amendments of the United States Constitution and are limited or barred by New Hampshire law.

44. To the extent plaintiffs seek exemplary or punitive damages, such damages are prohibited under New Hampshire law, N.H.R.S.A. Sec. 507:16, et seq.

45. To the extent plaintiffs seek exemplary or punitive damages, Mutual specifically incorporates by reference all standards and/or limitations regarding the determination and enforceability of punitive damage awards which arise in the decisions of *BMW of North America v. Gore*, 517 U.S. 559 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532

U.S. 424 (2001), and *State Farm Mut. Auto. Ins. Co. v. Campbell,* 123 S. Ct. 1513, 1519, 1521 (2003).

46. To the extent that the claims stated in the Complaint have been settled, compromised, or otherwise discharged, a set off is due.

47. Plaintiffs fail to state a claim upon which attorneys' fees can be awarded.

48. Mutual adopts and relies upon all provisions and defenses afforded it under Restatement of Torts 2d, § 402A, including the comments thereto.

49. Mutual reserves the right to raise all defenses provided in sections 2, 4, and 6 of the Restatement (Third) of Torts: Product Liability, if the Court finds that it is applicable in this case.

50. Mutual incorporates all defenses available under New Hampshire's liability law.

51. Plaintiffs' claims, if any, are barred, reduced and/or limited pursuant to any other applicable limitations of awards, caps on recovery, and setoffs permitted by law, including, but not limited to New Hampshire law regarding noneconomic loss or injury, and applicable New Hampshire law related to amounts paid or provided by collateral sources.

52. Mutual adopts and relies upon all provisions and defenses afforded it under the United States Constitution and the New Hampshire Constitution.

53. The product that is at issue in this litigation was not in an unreasonably dangerous condition.

54. Mutual's conduct was not the proximate or producing cause of plaintiffs' alleged injuries, if any.

55. Mutual's product was not defective in manufacture, design, construction, or formulation, and

it conformed to all representations made by Mutual, if any.

56. If plaintiffs suffered or sustained any injuries, loss, or damage as a result of the alleged incident referred to in plaintiffs' Complaint, the same were a direct result of plaintiffs' failure to follow the reasonable advice of her health care providers.

57. The injuries or damages sustained by plaintiffs, if any, may be attributed to several causes and accordingly should be apportioned among the various causes according to the respective contribution of each such cause to the harm sustained.

58. Plaintiffs failed to exercise ordinary care under the circumstances in using the product and such failure was the substantial cause of the occurrence that caused injury or damage, if any, to plaintiffs.

59. Plaintiffs' claims are barred by additional defenses that may arise during the course of this litigation, which Mutual reserves the right to assert.

60. Mutual incorporates the defenses of all others who are or may become parties to this action as though more fully set forth herein.

JURY DEMAND

A TRIAL BY JURY IS DEMANDED.

Respectfully submitted,

/s/ John E. Friberg, Sr.....
John E. Friberg, Sr.
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(603) 669-4140
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Mutual Pharmaceutical Company, Inc.

OF COUNSEL:
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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the above and foregoing instrument was served upon the following counsel of record via electronic case filing this 18th day of September, 2008.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

KAREN L. BARTLETT,

Plaintiff, **CASE NO.: 08-cv-358-JL**

vs. **Judge Joseph N. Laplante**

MUTUAL PHARMACEUTICAL COMPANY, INC., and UNITED RESEARCH LABORATORIES, INC.,

Defendants.

COMPLAINT – FIRST AMENDED

NOW COMES, Karen L. Bartlett complaining of the above-listed Defendants, and for causes of action would respectfully show this Honorable Court as follows:

GENERAL ALLEGATIONS

1. This is an action to recover damages for personal injuries sustained by Karen L. Bartlett, as the direct and proximate result of Defendants ' wrongful conduct in connection with the design, manufacture, sale, testing (or lack thereof), sale and distribution of the prescription drug Sulindac. Mrs. Bartlett is and was a resident of Plaistow, County of Rockingham, New Hampshire at all times material to the allegations set forth herein.

2. Defendant Mutual Pharmaceutical Company, Inc. is a Pennsylvania corporation with its principal place of business at 1100 Orthodox Street,

Philadelphia, PA 19124, which does business in New Hampshire.

3. Defendants United Research Laboratories, Inc. is a Pennsylvania corporation which also has its principal place of business at 1100 Orthodox Street, Philadelphia, PA 19124, which does business in New Hampshire.

Nature of the Case

FACTUAL BACKGROUND

4. At all times pertinent hereto Mutual Pharmaceutical Company, Inc. and/or United Research Laboratories, Inc. and their predecessors (collectively "Mutual & United" or the "Defendants") were engaged in the business of the testing, manufacturing, packaging, marketing, labeling, adverse drug event reporting or non-reporting, distribution, promotion, and/or sale of Sulindac.

5. Plaintiff Karen L. Bartlett, at the times alleged herein, lived in New Hampshire.

6. Ms. Bartlett was prescribed Defendant's product Sulindac in Plaistow, New Hampshire at Brooks Pharmacy.

7. Former Plaintiff Gregory S. Bartlett was at all relevant times married to plaintiff Karen L. Bartlett.

8. Mrs. Bartlett was prescribed a nonsteroidal anti-inflammatory drug (NSAID) for pain in her right shoulder secondary to bursitis. Dr. Mark Ergin prescribed her an NSAID called Sulindac. She filled that prescription for 60 Sulindac 200mg tablets at Brooks Pharmacy in Plaistow, New Hampshire, on December 30, 2004. Mrs. Bartlett, following the instructions of her gastroenterologist who performed a

routine colonoscopy on or about January 4, 2005, did not begin taking the Sulindac until 7 day after that procedure. Hence, she began taking sulindac on or about January 12, 2005. She ingested Sulindac, as prescribed, through on or about February 1, 2005.

9. Mrs. Bartlett presented to Holy Family Hospital emergency room with pimple like bumps, spots or blisters on her face, a fever, eye irritation, a sore throat, diarrhea, on February 1, 2005, they sent her home believing it was an allergic reaction. After Mrs. Bartlett called her doctor the following day she went back to Holy Family and was admitted on February 2, 2005. At Holy Family she was seen, repeatedly, by her primary care physician, Leo Lane, D.O. Dr. Lane and other health care professionals recognized that Mrs. Bartlett's condition was deteriorating rapidly and feared she that she may very well have Stevens Johnson Syndrome (SJS) progressing to Toxic Epidermal Necrolysis (TEN). A number of labs were done at Holy Family to rule out any viral or bacterial etiology of Mrs. Bartlett's condition. The result of same, according to the testimony of her treaters, effectively ruled out such non-medication causes of her illness.

10. On February 3, 2005, she was transferred by ambulance to New England Medical Center/Tufts where she was admitted to the ICU. More labs were done at Tufts. These labs also ruled out, according to the testimony of Dr. Deon Wolpowitz, any viral, bacterial or infectious etiology of Mrs. Bartlett's TEN. In fact, Tufts diagnosed the worst fears of Mrs. Bartlett's treaters at Holy Family – Karen Bartlett had TEN. Tufts did a skin biopsy. According to the testimony of Dr. Wolpowitz and Dr. John T. Schulz, III

(the latter was one of her three principal attending doctors at Harvard Medical School/Mass. General) skin biopsies are the most effective medical tool for confirming a diagnosis of TEN and ruling out other diseases, which unlike TEN, might be caused by things other than medications.

11. Mrs. Bartlett's Holy Family treaters tried to get her straight to Harvard/MA General (occasionally "MGH") but were advised there was no bed available. Hence, her one day at Tufts was a known conduit to get her into the burn unit at MGH. "Burn unit" is what it's called and that's what it is.

12. When someone gets TEN the standard of care requires that they be treated in a burn unit. According to testimony in this case there are only two burn units in Boston and a third hospital has a single "burn bed"

13. On February 4, 2005, Dr. Schulz admitted Mrs. Bartlett to MGH's burn unit. He ordered that she be placed here in a "burn bed" Burn beds at MGH's burn unit are bacteria controlled nursing units (BCNU), which are literally a plastic bubble used in an attempt to control bacteria, temperature and humidity. Dr. Schulz, in 2005, was one of the most published and most experienced burn surgeons in America, specifically pertaining to "what causes TEN" or its etiology, as well as the care, management and treatment of someone who has that disease.

14. Even though Dr. Lane referred Mrs. Bartlett to Dr. Ergin who prescribed the sulindac for shoulder pain, none of Mrs. Bartlett's doctors between February 1-3, 2009, elicited a history that she was on sulindac. Without such knowledge, obviously, none of them considered it as a potential cause of her SJS progressing to TEN. Although Dr. Wolpowitz at Tufts

records reflect that he was considering a different NSAID (other than sulindac) as the potential causative agent of Mrs. Bartlett's TEN – ibuprofen. But he did an addendum to his 2/3/05 note which stated that he had confirmed that Mrs. Bartlett took ibuprofen after her fever and rash began. In doing so he became the third health care provider in three days which took a history which stated that she took ibuprofen after her fever and rash began (the first was on 2/1/05 in the ER at Holy Family and the second was Dr. Mello's infectious disease consult on 2/2/05 at the same place). Drs. Wolpowitz and Mello both testified that ibuprofen taken on 2/1/05 can not cause fever and rash (virtually always a precursor to SJS/TEN) that began days earlier.

15. When Mrs. Bartlett arrived at MGH she was sedated. Shortly thereafter she was intubated and placed on a mechanical ventilator. As a consequence, she could not communicate with her health care providers. On admission, Dr. Schulz diagnosed TEN with 42% TBSA (total body surface area involvement). Dr. Schulz testified what that meant is that 42% of Mrs. Bartlett's skin was "an open wound" upon arrival. He testified this is synonymous with the fact that 42% of her skin had sloughed off. Two days later, on 2/6/06, Mrs. Bartlett had further detiorated. Dr. Schulz documented that 60-65% of her body was an open wound, restated, 60-65% of her skin had sloughed, exfoliated or fallen off. On 2/7/07 a nurse at MGH became the first health care provider in relation to TEN that figured out that Mrs. Bartlett had been taking sulindac. Her note that day says that a sulindac bottle was located with 60 tablets prescribed and 40 tablets missing. This accounts, give or take a

pill or two, for the pills that Ms. Bartlett took from on or about 1/12/05 through on or about 2/1/05.

16. One of Dr. Schulz many publications, before 2005, teaches that the skin has two layers; the outside layer, the epidermis and the second layer, the dermis. Dr. Schulz medical publication uses a lay analogy, he wrote the dermis is like the hull of a ship and the epidermis is like the paint on the hull. He testified that Mrs. Bartlett's conjunctival tissue was dieing or dead as a result of TEN, including in her eyes, her mouth, her oropharynx, her trachea and her vagina.

17. Dr. Schulz testified that it was his 2005 assessment, diagnosis and conclusion that his patient, Mrs. Bartlett had sulindac induced TEN. Dr. Schulz testified that it was his 2005 assessment that there was less than a 1 in 100 probability that anything other than sulindac, including every non-medication potential risk factor in the world, could have caused his patients TEN. Consistent with his 2005 conclusion that Mrs. Bartlett's TEN was caused by sulindac on or about 10/6/05 he made a medical note regarding this. On 10/3/05, after Karen had recently been discharged from over 100 days of hospitalizations at 4 hospitals (chronologically, Holy Family – 2 days, Tufts – 1 day, MGH – 70 days, NE Rehab – 4 days, MGH a second time – 9 days and Spaulding Rehabilitation Hospital - 23 days) Dr. Lane, her primary care physician, asked Mrs. Bartlett to ask her "specialists" in Boston about what drugs she should avoid in the future. Dr. Schulz note, 3 days later, states that he advised Mrs. Bartlett that her MedAlert bracelet needs to say "NSAIDs:SULINDAC". He also noted that he advised her as his note states that "[o]ther meds probably OK unless they have chemical structure resembling

sulindac". Dr. Schulz testified that the reason his 2005 medical records so state and the reason he so advised Mrs. Bartlett in 2005, was because he concluded in 2005 that Mrs. Bartlett's TEN was caused by sulindac.

18. Dr. Colleen Ryan was another of Mrs. Bartlett's MGH treating burn surgeons. Dr. Ryan testified that in 2005 she concluded that sulindac was the most likely cause of Karen Bartlett's TEN.

19. Mrs. Bartlett had four primary doctors who acted as her "attending physician" on any given day during her 70 day MGH burn unit hospitalization as well as during her second 9 day hospitalization there. They were Dr. Schulz, Dr. Ryan, Dr. Robert Sheridan and Dr. Nam Kim. Dr. Kim was a junior attending surgeon, senior fellow, with full admission, discharge and surgery privileges at MGH's burn unit in 2005. Dr. Kim testified that it was her belief and conclusion in 2005 that the most likely cause of her patient Mrs. Bartlett's TEN was sulindac.

20. Drs. Schulz, Ryan and Kim all testified that they had no knowledge of any member of Mrs. Bartlett's extensive MGH treatment team (including cardiologists, infectious disease doctors, anesthesiologists, other doctors and nurses) ever state, suggest or opine that anything other than sulindac causes Mrs. Bartlett's TEN.

21. Dr. Claes Dohlman and Dr. James Chodosh are two of Mrs. Bartlett's eye surgeons at MA Eye & Ear Infirmary. Together they have performed all of Mrs. Bartlett's most important post-SJS/TEN eye surgeries. She has had 11 such surgeries. Dr. Dohlman did the first four such surgeries, Dr. Chodosh has done another four of them. Her surgeries have included five corneal transplants, four "Dohlman/Boston Keratoprostheses"

a/k/a Boston Kpros and one "standard" or "traditional" cornea transplant. Dr. Dohlman and Dr. Chodosh both testified that they were 100% certain that Mrs. Bartlett's ocular lesions and legal blindness which have required these surgeries through August, 2009, are as a direct result of her SJS/TEN in 2005. Both Drs. Dohlman and Chodosh specifically testified that they were unaware of any healthcare professional at MA Eye & Ear who has ever made a conclusion contrary to the MA Eye & Ear record which states: "NSAIDs-sulindac caused Stevens Johnson Syndome"

22. Dr. John T. Schulz, III, testified that before he published a 2000 peer reviewed publication on TEN that he read every English publication in existence that related to TEN. Schulz, *et al., A Ten Year Experience with Toxic Epidermal Necrolysis*, J. Burn Care & Rehabilitation, 199-204 (May/June 2000). The first sentence of the publication reads: "[t]oxic epidermal necrolysis is a devastating *medication-induced* desquamation disorder with a reported mortality rate of 30-60% in adults." *Id.* at 199 (emphasis added). As is self-apparent from this sentence, Dr. Schulz testified that the precise reason for his words was to pronounce that TEN is not caused by anything other than medications. Dr. Schulz' peer reviewed publication on TEN states:

> TEN begins in response to medication exposure (Stevens-Johnson syndrome is similar but sometimes appears to have an infectious cause.)[footnote omitted] Hours to days after the first exposure, the patient experiences a flulike prodrome and then an eruption of erythematous macules [in lay terms bad blisters] that become confluent [meaning the blisters get so big they join each other]. Flaccid bullae develop that extend

with moderate digital pressure and indicate a positive Nikolsky's sign [meaning your skin sloughs off with moderate finger pressure]. The bullae soon rupture, which results in epitheal denudation of the affected areas. In 85% to 90% of patients with TEN, conjunctivae become inflamed. (Without care, symblepharon will follow [Dr. Schulz testified that means your eyelids fuse to your eyeballs]). Any mucosal surface [which includes the eyes, mouth, trachea, oropharynx and vagina] may slough, which leaves a macerated, unprotected surface. Progressive neutropenia and thrombocytopenia sometimes follow, and the patient can have septic complications from which 30% to 60% of those with TEN die.

Id. at 200.

23. Dr. Schulz testified that he was likely involved with Mrs. Bartlett's first cornea exam which occurred apparently within an hour of her arrival at MGH. He testified that nonetheless Mrs. Bartlett had symblepara (the fusing of her eyelids to her eyeballs).

24. Dr. Colleen Ryan's CV states that MGH's burn unit in conjunction with Shriner's Burn Hospital (primarily staffed through 2005 by Drs. Schulz, Sheridan and Ryan) has the highest survival rate of any burn unit in the world. Dr. Ryan confirmed this belief at her deposition and testified that Drs. Schulz and Sheridan played significant contributory roles in producing this result. With or without Dr. Ryan's testimony in this regard, Karen Bartlett likely received the best or some of the best care for TEN that could have been provided anywhere in the world from likely some of the best burn physicians in the world (Plaintiff asserts that no burn prominent burn surgeon in the world would exclude them from the top of the list or

very close to the top). Despite her outstanding care, the complications of Mrs. Bartlett's sulindac-induced TEN included:

- corneal melting,
- corneal scarring,
- symblephara,
- blindness,
- septic shock,
- esophageal sloughing;
- esophageal stricture,
- tracheal sloughing;
- tracheal plugging (when the sloughing becomes so extensive it can and does cause patients to asphyxiate);
- vocal chord paralysis,
- coma,
- vaginal injury,
- dyspareunia,
- respiratory dysfunction,
- scarring,
- disfigurement,
- GERD;
- pleural thickening;
- aspiration bronchiolitis;
- psychological trauma, and,
- post-traumatic stress disorder.

25. Not one of these conditions is warned of in Mutual's sulindac label or the NDA label for the same

drug that Mutual mimicked when Dr. Ergin chose sulindac to treat Mrs. Bartlett's shoulder pain on 12/30/04.

26. Drs. Schulz, Ryan and Kim all testified to the effect that they believed in 2005, that Karen Bartlett would have never required a single day of treatment in a burn unit, let alone 79 days there, if she had never ingested sulindac. Despite her outstanding care Mrs. Bartlett required the following treatment for her sulindac-induced TEN:

- treatment in a plastic bubble in the burn unit, specifically, a BCNU (bacteria controlled nursing unit);
- massive bleeding for literally months which required approximately 23 blood transfusions;
- horrifically painful wound dressing changes, which testimony establishes need to be "pulled off" your body at scheduled times and replaced;
- pig skin a/k/a a xenograft application to attempt to cover her wounds, prevent infection and promote scabbing;
- aquacel AG, a second type of artificial skin that contains silver nitrate;
- mepitel, a third type of artificial skin;
- acticoat, a fourth type of artificial skin;
- multiple "toilet bronchoscopies" (that is the term the doctors use) to attempt to combat the progressive tracheal sloughing and plugging);
- intubation;
- mechanical ventilation;

- all feeding through a line surgically implanted in her stomach or elsewhere which remained in for 11 months after her over 100 days of hospitalizations through April, 2006;
- pain, anxiolytlic and sedative medications in staggering amounts (approximately the following number of days on virtual constant IV doses of the following:
  - Morphine sulfate for 16 days (2/4/05-2/20/05);
  - Dilaudid for about 56 days (2/24/05-4/20/05);
  - Versed for about 54 days (2/4/05-3/28/05);
  - Valium for about 40 days (2/16/05-4/26/05);
  - Methadone for about 38 days (2/16/05-4/24/05); and
  - Lorezapam for about 6 days (4/19/05-4/24/05).

27. Defendants misled and failed to adequately warn the users of the potential serious dangers which Defendants knew or should have known might result from consuming its product. SJS and TENs are life threatening and often deadly conditions. However, Defendants violated the applicable code of federal regulations by failing to include a warning in the warning section of the label that these life threatening conditions were known side effects from the ingestion of Sulindac. Defendants did not need the FDA's approval to so strengthen its warning. Defendants had the unilateral right through the "Changes Being Affected" code of federal regulations to strengthen the risks disclosed in their PDR label and comply with the law by including these conditions in the warning section of the label.

28. As set forth in the report of Randall Tackett, Ph.D. and as Plaintiff alleges herein:

The proposition that a drug should not be withdrawn from the market because it treats pain is a false and dangerous notion. Seven NSAIDs, all with indications for various pain management have been withdrawn from the market. Four of these drugs were taken off the market in whole or in part, due to their risk of SJS/TEN (benoxaprofen, zomepirac acid, isoxicam and valdecoxib). Suprofen, a fifth, was removed, in part, due to photosensitivity a common SJS/TEN side effect; a sixth (bromfenac) has been associated with SJS, corneal melting and blindness, and ibufenac, the seventh was never marketed in the U.S.

• Mutual was negligent for failing to conduct any due diligence regarding whether they should initially apply for an ANDA for sulindac. Mutual was also negligent after they obtained their ANDA for sulindac in failing to conduct any NSAID or sulindac safety or medical literature analyses that would have resulted in a reasonable and prudent generic drug manufacturer removing sulindac from the market like seven other NSAIDs before it for many of the same reasons – ie the unnecessary risks of serious adverse reactions including SJS/TEN.

• Mutual should have taken unilateral and affirmative action to provide physicians and patients critically needed safety information about the level and degree of the SJS/TEN risk from sulindac and safer alternatives by taking the following acts and was negligent and grossly negligent for not doing so:

1) doing a CBE unilateral label change to add SJS and TEN to the warning section of the label (which

Mutual is and has been in violation of federal law by not having SJS and TEN in the warning section of the label);

2) sending a Dear Doctor letter;

3) sending a Dear Healthcare Professional letter;

4) filing and actively pursuing a Citizen's Petition for a label change (which other generic drug companies have done, like Mylan Pharmaceuticals, Inc., for another generic drug that both Mylan and Mutual market – metoclopramide/Reglan);

5) failing to study whether the benefits of sulindac outweigh its risks in relation to safer alternative medications for the same indications;

6) failing to study whether any subpopulation (like women) should be warned that they should have a blood or DNA test before being administered sulindac (such a Black Box Warning is in place for Tegretol/carbamazepine that says: "[DUE TO INCREASED RISK OF SJS & TEN] PATIENTS WITH ANCESTRY IN GENETICALLY AT RISK POPULATIONS SHOULD BE SCREENED FOR THE PRESENCE OF HLA-B*1502 PRIOR TO INITIATING TREATMENT WITH TEGRETOL.");

7) institute Pfizer-advocated actions to decrease SJS/TEN (on a different NSAID drug, valdecoxib, that was withdrawn from the market in large part due to SJS/TEN), including but not limited to a) limit use to patients who have failed to respond or could not tolerate other NSAIDs; b) requiring patient and physician educational efforts for more frequent and intense monitoring during the first 8 weeks of use (because prompt withdrawal of the offending agent is the most effective treatment for SCAR); c) requiring

information and patient/physician education materials to stress importance of immediate discontinuation at first evidence of dermal and/or mucosal signs or symptoms; and d) work with regulatory authorities to assure compliance with these measures;

8) institute, circulate and require a patient medication guide;

9) while subsumed by many of the points above, withholding from the FDA required information that was highly material and relevant to the performance of sulindac (because sulindac likely blinds or harms hundreds of people from SJS/TEN – one such clear example is withholding the Mockenhaupt, 2003, case-control study which reported that NSAIDs, including sulindac, have a statistically significant causal association with SJS/TEN); and

10) The risk benefit of sulindac does not justify the drug remaining on the market. In the very least, sulindac should have had a "Black Box Warning" about the causal relationship for SJS/TEN at least by 1991, immediately after Mutual received approval to market the drug. Mutual should have started to advocate for a Black Box Warning both upon completion of its due diligence before its initial ANDA filing and after its generic drug was approved for sale. Accordingly, it is my opinion that it was incumbent on Mutual to advocate to the FDA for both a Black Box Warning and a warning regarding SJS & TEN containing incidence information and subpopulation warnings.

29. Mutual knew or certainly should have known that SJS and TENS were side effects of Sulindac, the Defendants failed to amend their label to bring it in compliance with federal law. Accordingly, Ms.

Bartlett's prescribing physician was deprived of the ability to fully assess the risks when making the decision to prescribe these drugs due to the Defendants deficient and inadequate warning. Mutual's assertion that they are not liable because Dr. Ergin did not read Mutual's generic label is incorrect and illogical. It is incorrect given the labels were substantively identical and Mutual knew this (and substantively relied on this in support of their rejected "generic preemption" defense). Hence, when Dr. Ergin read the label for the RLD (Merck's Clinoril/sulindac) he was reading a substantively identical label for precise chemical for a product found to be bioequivalent to Mutual's sulindac. It is illogical, in part, because it relies on circular logic. Mutual says: are labels are "the same", in fact, there "identical" (but for irrelevant distinctions) but even though Dr. Ergin read "the same", "identical" label (which would have changed if we at Mutual got it changed) he needed to read "our" identical label for "us" to be liable. Nothing in the Hatch Waxman Act, nothing in 21 U.S.C. 355, *et. seq.* and nothing in the code of federal regulations supports such a defense.

30. As a result of the false and misleading claims made by Defendants regarding the safety and effectiveness of Defendant's product Sulindac, Ms. Bartlett suffered severe, painful and permanent injuries, specifically she sustained 65% total body surface area sloughing, TEN, symblephara, corneal scarring, corneal melts, ocular lesion, vision worse than legal blindess after 11 eye surgeries, esophageal stricture, vocal chord paralysis, respiratory and vaginal adhesion and other vaginal sequalae as a result of the ingestion of sulindac.

31. Had Ms. Bartlett known the risks and dangers associated with Defendant's product Sulindac through a medication guide that Mutual should have advocated and instituted, or had Defendants disclosed such information to Ms. Bartlett, she would not have taken Defendant's product Sulindac and would not have suffered her adverse reaction and its subsequent complications.

32. As a result of the manufacturing and marketing Defendant's product Sulindac, Defendants have reaped huge profits; while concealing from the public, knowledge of the potential hazard associated with the ingestion of Defendant's product Sulindac.

33. Defendants failed to perform adequate testing in that the adequate testing would have shown that Defendant's product Sulindac possessed serious side effects with respect to which Defendants should have taken appropriate measures to ensure that its defectively designed product would not be placed into the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

34. Prior to the manufacturing, sale and distribution of Defendant's Product Sulindac, Defendant, through its officers, directors and managing agents, had notice and knowledge from several sources, prior to the date of the marketing and sale of Defendant's Product Sulindac to Ms. Bartlett, that the products presented substantial and unreasonable risks of harm to the consumer. As such, said consumers, including Ms. Bartlett, were unreasonably subjected to risk of injury or death from the consumption of Defendant's Product Sulindac.

35. Despite such knowledge, Defendant, through its officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of Defendant's product Sulindac and failed to adequately warn the public, including Ms. Bartlett, of the serious risk of injury occasioned by the defects inherent in Defendant's product Sulindac. Defendants and its officers, agents and managers intentionally proceeded with the manufacturing, sale and marketing of Defendant's product Sulindac, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Ms. Bartlett, entitling her to exemplary or enhanced compensatory or enhanced compensatory damages.

36. Defendants acted with conscious and wanton disregard of the health and safety of Ms. Bartlett, who requests an award of additional damages for the sake of example and for the purpose of punishing such entities for its conduct, in an amount sufficiently large to be an example to others, and to deter Defendants and others from engaging in similar conduct in the future. The above-described wrongful conduct was done with knowledge, authorization, and ratification of officers, directors, and managing agents of Defendant.

37. As a result of ingesting the products manufactured, supplied, and/or sold by Defendant, Ms. Bartlett suffered severe, painful and permanent injuries, specifically a severe adverse reaction of erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute

generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, Stevens Johnson Syndrome or Toxic Epidermal Necrolysis. As a result of the dangerously defective nature of Defendant's product Sulindac at the time of manufacture and distribution, Ms. Bartlett, by using Sulindac, sustained the injuries and damages as herein alleged. To this day, Ms. Bartlett has trouble with scarring do to the effects of erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis.

38. As a direct and proximate result of Defendant's negligence as described herein, Ms. Bartlett has sustained harm, including permanent and debilitating injuries and ultimately her death. As a result of the acts and omissions of Defendant, Ms. Bartlett suffered severe, painful and permanent injuries, specifically a erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia, systemic symptoms of Stevens Johnson Syndrome or Toxic Epidermal Necrolysis and resultant injury, harm and economic loss as set forth herein.

LIABILITY OF GENERIC DRUG MANUFACTURER

39. Plaintiff incorporates the following authority in support of the proposition that ANDA holders have the unilateral authority to make CBE label changes to add to, enhance or increase safety information in a package insert or PDR label prior to approval of the label

changes by the FDA. Chronologically: *Wyeth v. Levine*, 129 S.Ct. 1187 (2009); *Kellogg v. Wyeth*, 612 F.Supp. 2d 437 (D.Vt. 2009); *Stacel v. Teva Pharmaceuticals, USA*, 620 F.Supp.2d 899 (N.Ill. 2009); *Schrock v. Wyeth, Inc.*, 601 F.Supp.2d 1262 (W.D.Ok. 2009); and *Bartlett v. Mutual Pharmaceutical Company, Inc.*, 2009 WL 3126305 (D.N.H. 2009).

40. Sulindac is a generic drug. The original Sulindac (marketed with the same name or under the name Clinoril) was sponsored by Merck and approved for use by the FDA in September, 1978.

41. Further, while the contention that generic holders can only enhance or add safety information to their labels is incorrect, it has virtually no support, when the RLD/NDA holder discontinues selling the drug. Sulindac has been marketed by Mutual in 150 mg and 200 mg dosage forms. Merck still markets 200 mg Clinoril/sulindac as of November, 2009. Merck no longer markets any 150 mg form of sulindac and/or Clinoril. Accordingly, Merck is not and has not been the RLD for 150 mg sulindac. The 2009 Orange Book does not identify an RLD for 150 mg sulindac. The Orange Book states:

THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH OFFICE OF PHARMACEUTICAL SCIENCE OFFICE OF GENERIC DRUGS. (emphasis in original)

42. For all of the reasons above, including the law cited above, Mutual & United had an ongoing duty to

conduct postmarketing safety surveillance for any reports of serious adverse events associated with Sulindac including any such report in the medical literature. The following is a non-exhaustive list of what Mutual & United knew or should have known and what should have compelled it to unilaterally change its label and warn physicians about the dangers and lack of efficacy of its drug Sulindac:

- Sulindac causes SJS and TEN.

- Virtually all of Karen Bartlett's sequalae of SJS & TEN listed above are direct consequences of SJS & TEN, virtually none of which are disclosed in Mutual's sulindac label or anything else Mutual has ever distributed to the public.

- All of Karen Bartlett's treatments she received for SJS & TEN are not disclosed in Mutual's sulindac label or anything else Mutual has ever distributed to the public.

- They are equally efficacious and far safer alternatives to sulindac, including aspirin and acetimonphen (Tylenol).

- Fifty percent of people with TEN suffer disabling ocular lesions.

- The mortality rate associated with SJS and TEN ranges between 30-80%.

- Per the FDA AERS database, Sulindac/Clinoril is the primary responsible drug for 172 cases of SJS and TEN including at least 39 deaths.

- Drs. Mockenhaupt and Stern published in their 2003 paper that evaluated the U.S. spontaneous reports, that the number of reports between 1980-1997 for Sulindac was 89 reports. They reported that

Sulindac had more reports than any other NSAID on the market in the U.S. during this time period, and that it ranked 5th of all drugs causing SJS and TEN in the U.S. FDA database. (Mockenhaupt et al., 2003)

Causes of Action

FIRST CLAIM FOR RELIEF
STRICT PRODUCT LIABILITY
FAILURE TO WARN

43. Ms. Bartlett incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

44. Defendants manufactured, marketed, distributed, and supplied Defendant's product Sulindac. As such, Defendants had a duty to warn the public including Ms. Bartlett of the health risks associated with using Defendant's product Sulindac.

45. Defendant's product Sulindac was under the exclusive control of Defendant, and was sold without adequate warnings regarding the risk of serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other risks associated with its use.

46. As a direct and proximate result of the defective condition of Defendant's product Sulindac, as manufactured and/or supplied by Defendant, and as a direct and proximate result of negligence, gross negligence, willful and wanton misconduct, or other wrongdoing and actions of Defendants described

herein, Ms. Bartlett suffered and economic loss as alleged herein.

47. Upon information and belief, Defendants knew of the defective nature of Defendant's product Sulindac but continued to design, manufacture, market, and sell Defendant's product Sulindac so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Defendant's product Sulindac and in violation of their duty to provide an accurate, adequate, and complete warning concerning the use of Defendant's product Sulindac.

48. Defendants failed to warn the public, Ms. Bartlett, or her prescribing physicians of the dangerous propensities of Defendant's product Sulindac, which dangers were known or should have been known to Defendant, as they were scientifically readily available.

49. Defendants knew and intended that Defendant's product Sulindac would be prescribed by physicians and would be used by persons with a prescription, without any inspection for defects. Defendants also knew that physicians and users such as Ms. Bartlett would rely upon the representations made by Defendants on the product labels and in other promotional and sales materials upon which the Ms. Bartlett and her prescribing physician did so rely.

50. As a direct and proximate result of the Defendant's sale of the product Sulindac without adequate warnings regarding the risk of serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms exfoliative dermatitis, toxic epidermal necrolysis,

Stevens-Johnson Syndrome and other risks associated with its use, Ms. Bartlett suffered harm as alleged herein, including ascertainable economic loss, including the purchase price of Defendant's product Sulindac, out-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Ms. Bartlett's ingestion of harmful and defective products, as well as extreme pain and suffering, loss of enjoyment of life, and other damages.

51. Defendant's conduct in the packaging, warning, marketing, advertising, promotion, distribution, and sale of Defendant's Product Sulindac, was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Ms. Bartlett, thereby entitling Ms. Bartlett to punitive damages in an amount to be determined at trial that is appropriate to reflect the aggravating circumstances herein.

SECOND CLAIM FOR RELIEF STRICT PRODUCT LIABILITY IN TORT, DEFECTIVE DESIGN AND MANUFACTURE

52. Ms. Bartlett incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

53. Mutual is liable in strict liability for the following reasons:

1. Mutual is in the business of selling the products;
2. Sulindac was in a defective condition unreasonably dangerous to the user/consumer;

3. The unreasonably dangerous condition existed when the defendant sold the product;
4. Sulindac reached the user/consumer, Karen Bartlett, without substantial change in the defective condition in which it was sold;
5. The unreasonably dangerous condition caused or substantially caused Karen Bartlett's, the plaintiff's, injury; and
6. The purpose and manner of Karen Bartlett's plaintiff's use of the product was an intended use and was reasonably foreseeable by Mutual.

54. Defendant's product Sulindac was sold, distributed, supplied, manufactured, marketed, and/or promoted by Defendant, and was expected to reach and did reach consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

55. The product Sulindac manufactured, supplied, and/or sold by Defendants was defective in design or formulation in that when it left the hands of the manufacturers and/or sellers and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation, the foreseeable risks exceeded the benefits associated with the designs or formulations of the product.

56. Upon information and belief, Defendants actually knew of the defective nature of Defendant's product Sulindac but continued to design, manufacture, market, and sell it so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Defendant's product Sulindac.

57. There were safer alternative methods and designs for the like product. At all times material, Sulindac was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a defective and unreasonably dangerous condition in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe and fit for its intended or reasonably foreseeable purpose or as intended to be used, thereby subjecting users and/or consumers of the drug, including Ms. Bartlett, to risks which exceeded the benefits of the drug;

b. The drug was insufficiently tested;

c. The drug caused harmful side effects that outweighed any potential utility;

d. The drug was not accompanied by adequate labeling, instructions for use and/or earnings to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Ms. Bartlett, of the potential risks and serious side effects associated with its use, thereby rendering Defendants liable to Ms. Bartlett.

e. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that Sulindac should not have been marketed in that condition.

58. At all times material, the drug Sulindac was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed, it was expected to reach, and did reach, users and/or consumers of the drug across the United States, including Ms. Bartlett, without substantial change in the defective and unreasonably dangerous condition in which it was sold.

59. At all times, Ms. Bartlett used Sulindac for its intended or reasonably foreseeable purpose. As a direct, legal proximate and producing result of the defective and unreasonably dangerous condition of Sulindac, Ms. Bartlett has sustained harm, including, among other things, acute, permanent and debilitating injuries, for which Ms. Bartlett is entitled to damages. These injuries have caused extensive pain and suffering, severe emotional distress, substantially reduced Ms. Bartlett's ability to enjoy life, and caused Ms. Bartlett to expend substantial sums of money for medical, hospital and related care.

60. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Sulindac, Ms. Bartlett has been injured in health, strength and activity and has suffered physical injuries as well as mental anguish. All of said injuries caused Ms. Bartlett intense anxiety, distress, fear, pain and suffering secondary to physical injury and damages, for which Ms. Bartlett is entitled to damages.

61. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition, Ms. Bartlett required reasonable and necessary health care treatment and services and

incurred expenses for which Ms. Bartlett is entitled to damages.

62. As a direct and proximate result of the design and manufacturing defects of Defendant's product Sulindac, Ms. Bartlett suffered harm as alleged herein, including ascertainable economic loss, including the purchase price of Defendant's product Sulindac, out-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Ms. Bartlett's ingestion of harmful and defective products, as well as extreme pain and suffering, loss of enjoyment of life, and other injuries.

63. Defendant's aforementioned conduct was wanton and committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Ms. Bartlett, including Defendant's knowingly withholding and/or misrepresenting information to the public including Ms. Bartlett, which information was material and relevant to the harm in question, enhanced compensatory damages in an amount to be determined at trial to appropriately reflect the aggravating circumstances herein.

THIRD CLAIM FOR RELIEF FRAUD

64. Ms. Bartlett incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

65. At all material times, Defendants were engaged in the business of manufacturing, marketing, distributing, promoting, and selling Defendant's product Sulindac.

66. Defendants made misrepresentations of material facts to, and omitted and/or concealed material facts from, Ms. Bartlett and her prescribing

physician in the advertising, marketing, distribution and sale of Defendant's product Sulindac regarding its safety and use.

67. Defendants deliberately and intentionally misrepresented to, and omitted and/or concealed material facts from, consumers, including Ms. Bartlett, and prescribing physicians, that Defendant's product Sulindac was safe when used as intended. Such misrepresentations, omissions, and concealments of facts include, but are not limited to:

a. Failing to disclose, and/or intentionally concealing, the results of tests showing the potential risks of serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other injuries associated with the use of Defendant's product Sulindac;

b. Failing to include adequate warnings with Defendant's product Sulindac about the potential and actual risks and the nature, scope, severity, and duration of serious adverse effects of Defendant's product Sulindac;

c. Concealing and/or providing false or inaccurate information regarding the known risks of serious skin reactions, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other risks associated with Defendant's product Sulindac; and

d. Concealing the known incidents of serious skin reactions, exfoliative dermatitis, toxic epidermal

necrolysis, Stevens-Johnson Syndrome and other injuries, as previously alleged herein.

68. Defendants intentionally concealed facts known to them, as alleged herein, in order to ensure increased sales of Defendant's product Sulindac.

69. Defendants had a duty to disclose the foregoing risks and failed to do so, despite possession of information concerning those risks. Defendant's representations that Defendant's product Sulindac was safe for its intended purpose were false, as Defendant's Product Sulindac was, in fact, dangerous to the health of Ms. Bartlett. Moreover, Defendants knew that their statements were false, knew of incidents of serious injuries, such as serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome, and knew that their omissions rendered their statements false or misleading.

70. Further, Defendants failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Defendant's Product Sulindac, and failed to disclose that Defendant's Product Sulindac caused serious skin reactions, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome, among other serious adverse effects. Defendants also failed to exercise reasonable care in communicating the information

concerning Defendant's product Sulindac to Ms. Bartlett, and/or concealed facts that were known to Defendant.

71. Ms. Bartlett was not aware of the falsity of the foregoing representations, nor was Ms. Bartlett aware that material facts concerning the safety of Defendant's product Sulindac had been concealed or omitted. In reliance upon Defendant's misrepresentations (and the absence of disclosure of the serious health risks), Ms. Bartlett ingested Defendant's Product Sulindac. Had Ms. Bartlett known the true facts concerning the risks associated with Defendant's product Sulindac, she would not have taken it.

72. The reliance by Ms. Bartlett upon Defendant's misrepresentations was justified because said misrepresentations and omissions were made by individuals and entities that were in a position to know the true facts concerning Defendant's product Sulindac. Ms. Bartlett was not in a position to know the true facts because Defendants aggressively promoted the use of Defendant's product Sulindac and concealed the risks associated with their use, thereby inducing Ms. Bartlett and her prescribing physician to use Defendant's product Sulindac.

73. As a direct and proximate result of Defendant's misrepresentations, and/or concealment, Ms. Bartlett suffered harm as alleged herein, including extreme pain and suffering, loss of enjoyment of life, ascertainable economic loss, including the purchase price of Defendant's Product Sulindac, out-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Ms. Bartlett's ingestion of Defendant's product Sulindac.

74. Defendant's aforementioned conduct was wanton and committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Ms. Bartlett, including Defendant's knowingly withholding and/or misrepresenting information to the public including Ms. Bartlett, which information was material and relevant to the harm in question, enhanced compensatory damages in an amount to be determined at trial to appropriately reflect the aggravating circumstances herein.

FOURTH CLAIM FOR RELIEF
Breach of Implied Warranty

75. Ms. Bartlett incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

76. Defendants manufactured, marketed, sold, and distributed Defendant's product Sulindac.

77. At the time Defendants marketed, sold, and distributed Defendant's product Sulindac for use by Ms. Bartlett, Defendants knew of the purpose for which Defendant's product Sulindac was intended and impliedly warranted Defendant's product Sulindac to be of merchantable quality and safe and fit for such use.

78. Ms. Bartlett and her prescribing physician reasonably relied on the skill, superior knowledge, and judgment of Defendants as to whether Defendant's product Sulindac was of merchantable quality and safe and fit for its intended use.

79. Ms. Bartlett used Defendant's product Sulindac which was provided to Ms. Bartlett's prescribing physician by the Defendant. Due to Defendant's wrongful conduct as alleged herein, Ms. Bartlett could

not have known about the risks and side effects associated with Defendant's product Sulindac until after Ms. Bartlett ingested it.

80. Contrary to such implied warranty, Defendant's product Sulindac was not of merchantable quality and was not safe or fit for its intended use.

81. As a direct and proximate result of Defendant's breach of implied warranty, Ms. Bartlett has suffered harm alleged herein, including extreme pain and suffering, loss of enjoyment of life, ascertainable economic loss, including the purchase price of Defendant's product Sulindac, out-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Ms. Bartlett's ingestion of harmful and defective products.

82. Defendant's aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Ms. Bartlett, thereby entitling Ms. Bartlett to punitive damages in an amount to be determined at trial that is appropriate to punish Defendants and deter them from similar conduct in the future.

FIFTH CLAIM FOR RELIEF
Breach of Express Warranty

83. Ms. Bartlett repeats and incorporates herein by reference the allegations made in the above Paragraphs.

84. Defendants expressly warranted that Sulindac was safe and well accepted by patients and was safe for long-term use.

85. Sulindac does not conform to these express representations because Sulindac is not safe and has high levels of serious, life-threatening side effects.

86. As a direct and proximate result of the breach of said warranties, Ms. Bartlett has been damaged, and is therefore entitled to damages as described herein

SIXTH CLAIM FOR RELIEF
Negligence

87. Ms. Bartlett incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

88. Defendants owed a duty to consumers of Defendant's product Sulindac, including Ms. Bartlett, to use reasonable care in designing, testing, labeling, manufacturing, marketing, supplying, distribution and selling Defendant's product Sulindac, including a duty to ensure that Defendant's Product Sulindac did not cause users to suffer from unreasonable, unknown, and/or dangerous side effects.

89. Defendants failed to exercise reasonable care in the warning about, designing, testing, labeling, manufacture, marketing, sale, and/or distribution of Defendant's product Sulindac and breached its duties to Ms. Bartlett in that, and not by way of limitation, they did not warn of the known risks associated with the use of Defendant's product Sulindac and did not exercise an acceptable standard of care, i.e., what a reasonably prudent manufacturer or seller would have known and warned about. Moreover, the product lacked sufficient warnings of the hazards and dangers to users of said product, and failed to provide safeguards to prevent the injuries sustained by Ms. Bartlett. Defendants failed to properly test Defendant's product Sulindac prior to its sale, and as a result subjected users to an unreasonable risk of injury when those products was used as directed and recommended.

90. Defendants additionally breached its duty and was negligent in its actions, misrepresentations, and omissions toward Ms. Bartlett, in part, in the following ways:

a. Failed to exercise due care in designing, developing, and manufacturing Defendant's Product Sulindac so as to avoid the aforementioned risks to individuals using these products;

b. Failed to include adequate warnings with Defendant's product Sulindac that would alert Ms. Bartlett and other consumers to its potential risks and serious side effects;

c. Failed to adequately and properly test Defendant's product Sulindac before placing it on the market;

d. Failed to conduct sufficient testing on Defendant's product Sulindac, which if properly performed, would have shown that Defendant's Product Sulindac had serious side effects, including, but not limited to, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other serious skin reactions;

e. Failed to adequately warn Ms. Bartlett and physicians that use of Defendant's product Sulindac carried a risk of serious skin reactions; erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, exfoliative

dermatitis, toxic epidermal necrolysis, Stevens-Johnson Syndrome and other serious side effects;

f. Failed to provide adequate post-marketing warnings or instructions after Defendants knew, or should have known, of the significant risks of reactions from the use of Defendant's product Sulindac;

g. Placed an unsafe product into the stream of commerce; and

h. Was otherwise careless or negligent.

91. Defendants knew, or should have known, that Defendant's product Sulindac caused unreasonably dangerous risks and serious side effects of which Ms. Bartlett would not be aware. Defendants nevertheless advertised, marketed, sold and/or distributed Defendant's product Sulindac knowing of its unreasonable risks of injury.

92. Defendants knew or should have known that consumers such as Ms. Bartlett would suffer injury as a result of Defendant's failure to exercise reasonable care as described above.

93. Upon information and belief, Defendants knew or should have known of the defective nature of Defendant's product Sulindac, as set forth herein, but continued to design, manufacture, market, and sell Defendant's product Sulindac so as to maximize sales and profits at the expense of the health and safety of the public, including Ms. Bartlett, in conscious and/or negligent disregard of the foreseeable harm caused by Defendant's product Sulindac.

94. Defendants failed to disclose to the Ms. Bartlett and the general public facts known or available to them, as alleged herein, in order to ensure continued and increased sales of Defendant's product Sulindac.

This failure to disclose deprived Ms. Bartlett of the information necessary for her to weigh the true risks of taking Defendant's product Sulindac against the benefits.

95. As a direct and proximate result of Ms. Bartlett's use of Defendant's product Sulindac, Ms. Bartlett suffered serious bodily injury including, but not limited to, erythema multiforme exudativum, bullous fixed drug eruption, severe cutaneous adverse reaction, acute generalized exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms, Stevens-Johnson Syndrome, a severe adverse reaction, and skin disorder.

96. By virtue of Defendant's negligence, Defendants has directly, foreseeably and proximately caused Ms. Bartlett to suffer serious bodily injury. As a result, the imposition of punitive damages against Defendants is warranted.

97. As a direct and proximate result of Defendant's negligence, Ms. Bartlett suffered harm as alleged herein, including severe pain and suffering, loss of enjoyment of life, ascertainable economic loss, including the purchase price of Defendant's product Sulindac, out- pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Ms. Bartlett's ingestion of harmful and defective products.

SEVENTH CLAIM FOR RELIEF
Gross Negligence and Wanton and Oppressive Actions and Non-Actions

98. Ms. Bartlett incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

99. Defendants had a duty to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of its Defendant's product Sulindac, including a duty to ensure that Defendant's product Sulindac did not cause users to suffer from unreasonable and dangerous side effects.

100. Defendants failed to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendant's Product Sulindac, in that Defendants knew or should have known that taking Defendant's Product Sulindac caused unreasonable and life-threatening injuries, as alleged herein.

101. Defendants wanton and oppressive acts as set forth herein relative to the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendant's product Sulindac in that they:

a. failed to provide adequate warnings with Defendant's Product Sulindac regarding their possible risks and adverse effects as well as the comparative severity and duration of such adverse effects;

b. failed to exercise due care in designing, developing, and manufacturing Defendant's product Sulindac so as to avoid the aforementioned risks to individuals;

c. placed unsafe product into the stream of commerce; and

d. was otherwise grossly negligent.

102. Although Defendants knew, or recklessly disregarded, the fact that Defendant's product Sulindac caused potentially lethal side effects,

Defendants continued to market Defendant's product Sulindac to consumers, including Ms. Bartlett, without disclosing these side effects.

103. Defendants knew and/or consciously or recklessly disregarded the fact that consumers such as Ms. Bartlett would suffer injury as a result of Defendant's failure to exercise reasonable care as described above.

104. Defendants knew of, or recklessly disregarded the defective nature of Defendant's product Sulindac, as set forth herein, but continued to design, manufacture, market, and sell Defendant's Product Sulindac so as to maximize sales and profits at the expense of the health and safety of the public, including Ms. Bartlett, in conscious and/or reckless disregard of the foreseeable harm caused by Defendant's product Sulindac.

105. As a direct and proximate result of the gross negligence, willful and wanton misconduct, or other wrongdoing and actions of Defendants described herein, which constitute a deliberate act or omission with knowledge of a high degree probability of harm and reckless indifference to the consequences, Ms. Bartlett suffered harm as previously alleged herein, including ascertainable economic loss, including the purchase price of Defendant's product Sulindac, out-of-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Ms. Bartlett's ingestion of Defendant's harmful and defective product Sulindac. In addition, Ms. Bartlett has been rendered sick, blistered and scarred, both internally and externally. All of said injuries have caused and continue to cause Ms. Bartlett intense anxiety, distress, fear, pain, suffering, and distress

secondary to the physical injury and damages. In addition, Ms. Bartlett has suffered other injuries; the exact nature and extent are not known at this time.

106. As a direct and proximate result of the gross negligence, willful and wanton misconduct, or other wrongdoing and actions of Defendant, which constitute a deliberate act or omission with knowledge of a high degree probability of harm and reckless indifference to the consequences, Ms. Bartlett will in the future be required to obtain medical and/or hospital care, attention, and services. As a result, Ms. Bartlett may incur expenses for such health care treatment in an amount as yet unascertained.

107. Defendant's aforementioned conduct was wanton and committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Ms. Bartlett, including Defendant's knowingly withholding and/or misrepresenting information to the public including Ms. Bartlett, which information was material and relevant to the harm in question, enhanced compensatory damages in an amount to be determined at trial to appropriately reflect the aggravating circumstances herein.

DAMAGES

108. As a direct and proximate result of Plaintiff's ingestion and use of Defendant's defective product, Plaintiff sustained the following damages and seek recovery thereon:

1. Past emotional distress;
2. Future emotional distress, including without limitation, justifiable fear of disease;

3. The infliction of numerous diseases and illnesses, summarized herein, which will in all likelihood be permanent;
4. Blindness;
5. Loss of Enjoyment of Life;
6. Physical and Mental Pain and Suffering;
7. Inconvenience;
8. Past lost income;
9. Future lost income and earning capacity;
10. Past mental anguish;
11. Future mental anguish;
12. Disfigurement;
13. Physical pain and suffering;
14. Past medical expenses; and
15. Future medical expenses.

Enhanced Compensatory Damages

93. Plaintiff hereby incorporates by this reference all other paragraphs of this Complaint as if fully set forth herein at length.

94. At all times relevant hereto, Defendants had actual knowledge of the defective and dangerous nature of Sulindac as set forth herein and continued to design, manufacture, market, promote, distribute and sell it so as to maximize sales and profits at the expense of the public's health and safety and in conscious disregard for the foreseeable serious harm caused by the drug. Defendant's conduct was much more probably than not wanton, malicious, or oppressive. Defendants' conduct was "wanton" as it evidenced and demonstrated a reckless indifference or

disregard of consequences. Defendants' conduct was "malicious" as it evidenced and demonstrated ill-will, hatred, hostility, or bad motive. Defendants' conduct was "oppressive" as it evidenced and demonstrated an abuse of power.

95. The Defendant's conduct exhibits such an entire want of care as to establish that its actions were a result of malice, fraud, ill will, recklessness, and/or willful and intentional disregard for the safety and rights of consumers of its drugs such as the decedent. Plaintiff therefore seeks to recover enhanced compensatory damages to the fullest extent permitted by law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, KAREN L. BARTLETT, prays for relief as follows:

a. Awarding actual and compensatory damages to Plaintiff incidental to Ms. Bartlett's purchase and ingestion of Defendants' product in an amount to be determined at trial;

b. Awarding enhanced compensatory damages to Plaintiff;

c. Awarding pre-judgment and post-judgment interest to Plaintiff;

d. Awarding the costs and expenses of this litigation to Plaintiff;

e. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and

f. For such further relief as this Court deems necessary, just, and proper.

Respectfully submitted,

/s/ Keith M. Jensen
Keith M. Jensen
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Pro hac vice
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603 749-5000

ATTORNEY TO BE NOTICED

ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF SERVICE

I certify that this document was provided to counsel for Mutual on November 15, 2009, to confer on whether they would assent to its filing and if that if Mutual does not assent it will be an attachment to a motion for leave of Court to file same filed on November 16, 2009.

/s/ Keith M. Jensen
Keith M. Jensen

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW HAMPSHIRE

KAREN L. BARTLETT

and **CASE NO. 08-cv-358-JL**

GREGORY S. BARTLETT,

Plaintiffs **Judge Joseph N. Laplante**

vs.

MUTUAL PHARMACEUTICAL COMPANY, INC., UNITED RESEARCH LABORATIRES, INC., and BROOKS PHARMACY,

Defendants.

ANSWER OF MUTUAL PHARMACEUTICAL COMPANY INC., TO PLAINTIFFS' FIRST AMENDED COMPLAINT

Mutual Pharmaceutical Company, Inc. ("Mutual"), answers plaintiffs' First Amended Complaint ("FAC") as follows:

Mutual incorporates the following into its response to each paragraph below: Mutual denies each allegation in the FAC except those expressly admitted. Mutual also states that to the extent that allegations in the FAC refer generally to "Defendants," Mutual answers said allegations only as to itself. To the extent the allegations in the FAC refer to defendants or entities other than Mutual, Mutual states that it lacks

knowledge or information sufficient to form a belief as to the truth of those allegations.[1]

GENERAL ALLEGATIONS

1. Mutual admits that plaintiffs seek recovery pursuant to various legal theories. Further, Mutual admits that sulindac is a generic prescription drug and that upon information and belief Ms. Bartlett is a resident of the County of Rockingham, New Hampshire. Mutual denies the remaining allegations in Paragraph 1 of the FAC.

2. Mutual admits that it is a Pennsylvania corporation with its principal place of business at 1100 Orthodox Street, Philadelphia, PA 19124. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 2 of the FAC.

3. Mutual admits that United Research Laboratories, Inc. ("United"), is a Pennsylvania corporation with its principal place of business at 1100 Orthodox Street, Philadelphia, PA 19124. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 3 of the FAC.

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[1] Mutual notes that plaintiffs have unilaterally and improperly purported to eliminate or dismiss plaintiff Greg Bartlett from this litigation by changing the caption of the case in the FAC to exclude Mr. Bartlett. While Mutual concedes that the parties' January 8, 2010, stipulation required Mutual to answer the FAC, it also required that plaintiffs file a motion to dismiss Greg Bartlett as a plaintiff after the completion of his deposition. (*See* January 7, 2010, Minute Entry.) Greg Bartlett's deposition is currently set for February 17, 2010.

Nature of Case

FACTUAL BACKGROUND

4. Mutual admits that it has engaged in the testing, manufacturing, packaging, and distribution of sulindac. The allegations in Paragraph 4 of plaintiffs' FAC regarding alleged "predecessors" constitute purported legal conclusions rather than allegations of fact to which no answer by Mutual is required. To the extent an answer is required, Mutual denies those allegations. Mutual admits that plaintiffs purport to identify Mutual, United, and "their predecessors" collectively as "Defendants" but denies that such characterization is complete or accurate. Mutual denies the remaining allegations in Paragraph 4 of the FAC.

5. Mutual admits upon information and belief that plaintiff Karen L. Bartlett lived in New Hampshire. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 5 of the FAC.

6. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 of the FAC.

7. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7 of the FAC.

8. Mutual admits that sulindac is a prescription nonsteroidal anti-inflammatory drug ("NSAID"), but denies that Dr. Mark Ergin prescribed "sulindac" to Ms. Bartlett. To the contrary, Dr. Ergin prescribed Clinoril. Mutual admits that Ms. Bartlett's gastroenterologist warned her not to take any NSAIDS for a period of time before and after her colonoscopy.

Mutual lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 8 of the FAC.

9. Mutual denies that plaintiffs have accurately or completely set forth or characterized Ms. Bartlett's medical condition, onset of symptoms, and medical treatment on February 1-2, 2005, in Paragraph 9 of the FAC. Mutual denies any remaining allegations in Paragraph 9 of the FAC.

10. Mutual denies that plaintiffs have accurately or completely set forth or characterized Ms. Bartlett's medical condition, onset of symptoms, and medical treatment on February 3, 2005, in Paragraph 10 of the FAC. Mutual denies any remaining allegations in Paragraph 10 of the FAC.

11. Mutual denies that plaintiffs have accurately or completely set forth or characterized Ms. Bartlett's medical condition, onset of symptoms, and medical treatment on February 3, 2005, in Paragraph 11 of the FAC. Mutual denies any remaining allegations in Paragraph 11 of the FAC.

12. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of the FAC, and, accordingly denies those allegations.

13. Mutual denies that plaintiffs have accurately or completely set forth or characterized Ms. Bartlett's medical condition, onset of symptoms, and medical treatment on February 4, 2005, in Paragraph 13 of the FAC. Mutual denies any remaining allegations in Paragraph 13 of the FAC.

14. Mutual denies that Dr. Ergin prescribed "sulindac" to Ms. Bartlett. Mutual admits that none of

Ms. Bartlett's doctors between February 1-3, 2005, elicited a history that she was on sulindac. Mutual denies that none of her treaters considered her condition to be an adverse drug reaction. Mutual admits that Dr. Wolpowitz at Tufts recorded that he considered ibuprofen to be the cause of her condition. Mutual denies that plaintiffs have completely or accurately set forth or characterized Ms. Bartlett's medical condition, onset of symptoms, and medical treatment on February 1-3, 2009, in paragraph 14 of the FAC. Mutual further denies that plaintiffs have completely or accurately set forth, summarized, or characterized the medical records and testimony of Drs. Wolpowitz and Mello. Mutual denies any remaining allegations in Paragraph 14 of the FAC.

15. Mutual denies that plaintiffs have accurately or completely set forth or characterized Ms. Bartlett's medical condition, onset of symptoms, and medical treatment on February 4-6, 2005, in Paragraph 15 of the FAC. Mutual further denies that plaintiffs have accurately or completely set forth Mrs. Bartlett's alleged ingestion of sulindac. Mutual denies any remaining allegations in Paragraph 15 of the FAC.

16. Mutual denies that plaintiffs have completely or accurately set forth, summarized, or characterized the medical records and testimony of Dr. Schulz. Mutual denies any remaining allegations in Paragraph 16 of the FAC.

17. Mutual denies that plaintiffs have completely or accurately set forth, summarized, or characterized the medical records and testimony of Dr. Schulz. Mutual denies any remaining allegations in Paragraph 17 of the FAC.

18. Mutual admits that Dr. Colleen Ryan was a treating physician of Mrs. Bartlett. Mutual denies that plaintiffs have completely or accurately set forth, summarized, or characterized the medical records and testimony of Dr. Ryan. Mutual denies any remaining allegations in Paragraph 18 of the FAC.

19. Mutual admits that Dr. Schulz, Dr. Ryan, Dr. Sheridan, and Dr. Kim treated Mrs. Bartlett in 2005. Mutual denies that plaintiffs have completely or accurately set forth, summarized, or characterized the medical records and testimony of any of those doctors. Mutual denies any remaining allegations in Paragraph 19 of the FAC.

20. Mutual denies that plaintiffs have completely or accurately set forth, summarized, or characterized the medical records and testimony of Dr. Schulz, Dr. Ryan, Dr. Sheridan, or Dr. Kim. Mutual denies any remaining allegations in Paragraph 20 of the FAC.

21. Mutual admits that Dr. Claes Dohlman and Dr. James Chodosh are two of Mrs. Bartlett's treating physicians at Mass Eye & Ear Infirmary. Mutual denies that plaintiffs have completely or accurately set forth, summarized, or characterized the medical records and testimony of Dr. Dohlman or Dr. Chodosh. Mutual denies any remaining allegations in Paragraph 21 of the FAC.

22. Mutual denies that plaintiffs have completely or accurately set forth, summarized, or characterized the testimony of Dr. Shulz or the medical literature referenced in Paragraph 22 of the FAC. Mutual denies any remaining allegations in Paragraph 22 of the FAC.

23. Mutual denies that plaintiffs have completely or accurately set forth, summarized, or characterized the

testimony of Dr. Shulz in Paragraph 23 of the FAC. Mutual denies any remaining allegations in Paragraph 23 of the FAC.

24. Mutual denies that plaintiffs have completely or accurately set forth, summarized, or characterized Dr. Ryan's CV, testimony, or Mrs. Bartlett's medical treatment or conditions in Paragraph 24 of the FAC. Mutual denies any remaining allegations in Paragraph 24 of the FAC.

25. Mutual denies the allegations in Paragraph 25 of the FAC. Answering further, all of the conditions referenced in Paragraph 25 of the FAC are well known sequallae of SJS/TEN, and SJS/TEN is specifically warned about in the sulindac label.

26. Mutual denies that plaintiffs have completely or accurately set forth, summarized, or characterized the testimony of Drs. Shulz, Ryan, and Kim in Paragraph 26 of the FAC. Mutual denies any remaining allegations in Paragraph 26 of the FAC.

27. Mutual denies the allegations in Paragraph 27 of the FAC.

28. Mutual denies the allegations in Paragraph 28 of the FAC.

29. Mutual denies the allegations in Paragraph 29 of the FAC.

30. Mutual denies the allegations in Paragraph 30 of the FAC.

31. Mutual denies the allegations in Paragraph 31 of the FAC.

32. Mutual denies the allegations in Paragraph 32 of the FAC.

33. Mutual denies the allegations in Paragraph 33 of the FAC.

34. Mutual denies the allegations in Paragraph 34 of the FAC.

35. Mutual denies the allegations in Paragraph 35 of the FAC.

36. Mutual denies the allegations in Paragraph 36 of the FAC.

37. Mutual denies the allegations in Paragraph 37 of the FAC.

38. Mutual denies the allegations in Paragraph 38 of the FAC.

LIABILITY OF GENERIC DRUG MANUFACTURER

39. The allegations in Paragraph 39 of the FAC constitute purported legal conclusions rather than allegations of fact to which no answer by Mutual is required. To the extent an answer is required, Mutual denies the allegations. Mutual denies any remaining allegations in Paragraph 39.

40. Mutual admits that sulindac is a generic drug. Mutual admits that the brand-name version of sulindac is Clinoril, which was approved by the FDA in September, 1978. Mutual lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 40 of the FAC.

41. Mutual admits that it has marketed sulindac in 150 mg and 200 mg dosage forms. Mutual denies the remaining allegations in Paragraph 41 of the FAC.

42. The allegations in Paragraph 24 of the FAC constitute purported legal conclusions rather than allegations of fact to which no answer by Mutual is

required. To the extent an answer is required, Mutual denies the allegations. Mutual denies any remaining allegations in Paragraph 42.

CAUSES OF ACTION

FIRST CLAIM FOR RELIEF

STRICT PRODUCT LIABILITY – FAILURE TO WARN

43. Mutual incorporates its responses to Paragraphs 1 through 42 of the FAC as if fully set forth herein.

44. Mutual admits only that it has manufactured and distributed sulindac. The balance of Paragraph 44 states purported conclusions of law to which no response is required or necessary. To the extent a response is required, Mutual denies those allegations. Mutual denies any remaining allegations in Paragraph 44.

45. Mutual denies the allegations in Paragraph 45 of the FAC.

46. Mutual denies the allegations in Paragraph 46 of the FAC.

47. Mutual denies the allegations in Paragraph 47 of the FAC.

48. Mutual denies the allegations in Paragraph 48 of the FAC.

49. Mutual admits only that sulindac is a prescription drug. Mutual denies the remaining allegations in Paragraph 49 of the FAC.

50. Mutual denies the allegations in Paragraph 50 of the FAC.

51. Mutual denies the allegations in Paragraph 51 of the FAC.

SECOND CLAIM FOR RELIEF

STRICT PRODUCT LIABILITY – DEFECTIVE IN DESIGN OR MANUFACTURE

52. Mutual incorporates its responses to Paragraphs 1 through 51 of the FAC as if fully set forth herein.

53. Mutual denies the allegations in Paragraph 53 of the FAC.

54. Mutual is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning whether sulindac reached consumers without substantial change in condition. Mutual denies the remaining allegations in Paragraph 54 of the FAC.

55. Mutual denies the allegations in Paragraph 55 of the FAC.

56. Mutual denies the allegations in Paragraph 56 of the FAC.

57(a)-(e). Mutual denies the allegations in Paragraph 57(a)-(e) of the FAC.

58. Mutual denies the allegations in Paragraph 58 of the FAC.

59. Mutual is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning the manner in which plaintiff allegedly used sulindac. Mutual denies the remaining allegations in Paragraph 59 of the FAC.

60. Mutual denies the allegations in Paragraph 60 of the FAC.

61. Mutual denies the allegations in Paragraph 61 of the FAC.

62. Mutual denies the allegations in Paragraph 62 of the FAC.

63. Mutual denies the allegations in Paragraph 63 of the FAC.

THIRD CLAIM FOR RELIEF FRAUD

64. Mutual incorporates its responses to Paragraphs 1 through 63 of the FAC as if fully set forth herein.

65. Mutual admits only that it has manufactured, sold, and distributed sulindac. Mutual denies the remaining allegations in Paragraph 65 of the FAC.

66. Mutual denies the allegations in Paragraph 66 of the FAC.

67(a)-(d). Mutual denies the allegations in Paragraph 67(a)-(d) of the FAC.

68. Mutual denies the allegations in Paragraph 68 of the FAC.

69. Paragraph 69 of the FAC contains statements of purported legal conclusions rather than allegations of fact regarding duties allegedly imposed upon Mutual by law to which no answer by Mutual is required. To the extent an answer is required, Mutual denies those allegations. Mutual denies all other allegations in Paragraph 69.

70. Mutual denies the allegations in Paragraph 70 of the FAC.

71. Mutual denies the allegations in Paragraph 71 of the FAC.

72. Mutual denies the allegations in Paragraph 72 of the FAC.

73. Mutual denies the allegations in Paragraph 73 of the FAC.

74. Mutual denies the allegations in Paragraph 74 of the FAC.

FOURTH CLAIM FOR RELIEF BREACH OF IMPLIED WARRANTY

75. Mutual incorporates its responses to Paragraphs 1 through 74 of the FAC as if fully set forth herein.

76. Mutual admits only that it has manufactured, sold, and distributed sulindac. Mutual denies the remaining allegations in Paragraph 76 of the FAC.

77. Paragraph 77 of the FAC contains statements of purported legal conclusions rather than allegations of fact regarding an alleged implied warranty to which no answer by Mutual is required. To the extent an answer is required, Mutual denies those allegations. Mutual denies all other allegations in Paragraph 77.

78. Mutual denies the allegations in Paragraph 78 of the FAC.

79. Mutual denies the allegations in Paragraph 79 of the FAC.

80. Mutual denies the allegations in Paragraph 80 of the FAC.

81. Mutual denies the allegations in Paragraph 81 of the FAC.

82. Mutual denies the allegations in Paragraph 82 of the FAC.

FIFTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY

83. Mutual incorporates its responses to Paragraphs 1 through 82 of the FAC.

84. Mutual denies the allegations in Paragraph 84 of the FAC.

85. Mutual denies the allegations in Paragraph 85 of the FAC.

86. Mutual denies the allegations in Paragraph 86 of the FAC.

SIXTH CLAIM FOR RELIEF NEGLIGENCE

87. Mutual incorporates its responses to Paragraphs 1 through 86 of the FAC as if fully set forth herein.

88. Paragraph 88 of the FAC states conclusions of law to which no response is required or necessary. To the extent a response is required, Mutual denies the allegations in Paragraph 88. Mutual denies all other allegations in Paragraph 88.

89. Mutual denies the allegations in Paragraph 89 of the FAC.

90(a)-(h). Mutual denies the allegations in Paragraph 90(a)-(h) of the FAC.

91. Mutual denies the allegations in Paragraph 91 of the FAC.

92. Mutual denies the allegations in Paragraph 92 of the FAC.

93. Mutual denies the allegations in Paragraph 93 of the FAC.

94. Mutual denies the allegations in Paragraph 94 of the FAC.

95. Mutual denies the allegations in Paragraph 95 of the FAC.

96. Mutual denies the allegations in Paragraph 96 of the FAC.

97. Mutual denies the allegations in Paragraph 97 of the FAC.

SEVENTH CLAIM FOR RELIEF

Gross Negligence and Wanton and Oppressive Action and Non-Actions

98. Mutual incorporates its responses to Paragraphs 1 through 97 the FAC as if fully set forth herein.

99. Paragraph 99 of the FAC states conclusions of law to which no response is required or necessary. To the extent a response is required, Mutual denies the allegations in Paragraph 99. Mutual denies all other allegations in Paragraph 99.

100. Mutual denies the allegations in Paragraph 100 of the FAC.

101(a)-(d). Mutual denies the allegations in Paragraph 101(a)-(d) of the FAC.

102. Mutual denies the allegations in Paragraph 102 of the FAC.

103. Mutual denies the allegations in Paragraph 103 of the FAC.

104. Mutual denies the allegations in Paragraph 104 of the FAC.

105. Mutual denies the allegations in Paragraph 105 of the FAC.

106. Mutual denies the allegations in Paragraph 106 of the FAC.

107. Mutual denies the allegations in Paragraph 107 of the FAC.

Damages

108(1)-(15). Mutual denies the allegations in Paragraph 108(1)-(15) of the FAC.

Enhanced Compensatory Damages

93. (improperly numbered 93 in the FAC). Mutual incorporates its responses to Paragraphs 1 through 108(1)-(15) of the FAC as if fully set forth herein.

94. Mutual denies the allegations in Paragraph 94 of the FAC.

95. Mutual denies the allegations in Paragraph 95 of the FAC.

PRAYER FOR RELIEF

Mutual admits that plaintiffs seek the relief requested in the corresponding paragraph of the Complaint beginning, "WHEREFORE," but denies that plaintiffs are entitled to the relief requested, or any recovery whatsoever.

DEFENSES

Pleading further, Mutual Pharmaceutical Company, Inc. ("Mutual"), asserts the following defenses to plaintiffs' FAC and reserves its right to amend or supplement these defenses as further information becomes available through discovery:

1. Plaintiffs' FAC fails to state a claim upon which relief can be granted.

2. Plaintiffs have failed to plead her claims with sufficient particularity.

3. Plaintiffs lack standing and/or capacity to assert the claims alleged in the FAC.

4. Plaintiffs' claims are barred by the doctrine of unclean hands, laches, waiver and/or estoppel.

5. Any claim or cause of action that plaintiffs may have had is barred by the applicable statutes of limitation and/or statues of repose.

6. Lack of privity between plaintiffs and Mutual bars any claims based on contractual or warranty theories.

7. The product at issue in this litigation has been formulated, designed, tested, manufactured, processed, distributed, and labeled in accordance with the provisions of the federal Food, Drug and Cosmetic Act and any regulations promulgated thereunder. Therefore, plaintiffs' claims are preempted or barred by federal law and regulation.

13. Plaintiffs' claims are barred because at the time the product at issue in this litigation left Mutual's control, it complied with applicable codes, standards, regulations, and specifications established, adopted, promulgated, or approved by the United States or by New Hampshire law, or by any agency of the United States or New Hampshire. The product was reasonably fit, suitable, and safe for its intended purpose.

14. The product at issue in this litigation was modified, altered, or changed from the condition in which it was sold, which modification, alteration, or change caused or contributed to cause plaintiffs' alleged damages.

15. The product at issue in this litigation conformed precisely in all ways to its specifications and performance standards and posed no danger in its manufacture and composition.

16. Plaintiffs' claims are barred because at the time the product at issue in this litigation left Mutual's control, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which plaintiffs seek to

recover damages without substantially impairing the reasonably anticipated or intended function of the product.

17. Plaintiffs' damages, if any, were caused by inherent characteristics of the product that are generic aspects of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability. Further, all reasonable precautions consistent with legal duties and obligations were taken to protect third parties from any dangers posed by the inherent characteristics of the product.

18. The benefits of the product outweigh the risk of danger or harm, if any, inherent in the product.

19. There is no duty to warn about any possible dangers that were not known at the time of manufacture and sale of product in question.

20. Any communications and/or actions between any of the defendants and the United States Food and Drug Administration and/or any governmental agency or entity are constitutionally protected under the Noerr-Pennington Doctrine and the First Amendment to the United States Constitution.

21. The product at issue in this litigation was sold in a reasonable and prudent manner based upon available medical and scientific knowledge and further were processed in accordance with and pursuant to all applicable regulations of the Federal Food and Drug Administration.

22. Based on the state of scientific, medical, and technological knowledge at the time it was marketed, the product at issue in this litigation was reasonably safe for its normal and foreseeable uses. In light of the

existing reasonably available medical, scientific, and technological knowledge, the design characteristics, if any, that allegedly caused the damages plaintiffs complain of, or the alleged risk of such characteristics, could not have been known.

23. Mutual's actions conformed to the state of the art of reasonably available scientific and technological knowledge at all times relevant to this lawsuit. At the time the product left the control of Mutual, the product was in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, or labeled.

24. Mutual at all times discharged its duty to warn through appropriate and adequate warnings in accordance with federal statutes and regulations consistent with the existing state of medical and scientific knowledge.

25. If plaintiffs sustained damages by reason of the matters alleged in the FAC, which is denied, then said damages were caused solely by or contributed to by the acts or fault of third parties and were not caused or contributed to by any acts or fault of Mutual, its officers, agents, contractors, servants, employees, or others for whom it was responsible.

26. Plaintiffs' damages, if any, were proximately caused by unforeseeable, independent, intervening, or superseding events beyond the control, and unrelated to the conduct of Mutual. The actions and omissions of Mutual, if any, were superseded by such unforeseeable, independent, intervening, and superseding events.

27. The injuries and damages claimed by plaintiffs resulted from their own conduct so that plaintiffs'

claims are barred, in whole or in part, by the comparative negligence, plaintiffs' misconduct, fault, or responsibility of causation attributed to plaintiffs. Thus, plaintiffs' claims should be dismissed, reduced, offset, or barred in accordance with the principles of comparative negligence. Plaintiffs' recovery of damages, if any exist, must be reduced by the comparative negligence and/or fault of plaintiffs and other persons, including responsible non-parties, pursuant to New Hampshire law.

28. The injuries and damages claimed by plaintiffs were caused, in whole or in part, by the acts or omissions of persons other than Mutual, over whom Mutual, had no control. Therefore, any recovery by plaintiffs should be apportioned in direct proportion to such fault in accordance with applicable law.

29. Any injuries or damages sustained by plaintiffs were directly and proximately caused by the failure of plaintiffs to heed warnings and instructions. Therefore, no recovery is available to plaintiffs.

30. If plaintiffs sustained damages as alleged in plaintiffs' FAC, which is denied, plaintiffs failed to mitigate their damages.

31. Plaintiff's misuse of the product, which was not reasonably foreseeable, caused plaintiffs' alleged damages, if any, and plaintiffs' claims therefore may be barred or reduced by applicable law.

32. Plaintiffs' claims are barred to the extent the injuries alleged in the FAC were caused or enhanced by pre-existing or unrelated medical, genetic, environmental, or psychiatric conditions, diseases or illnesses, by plaintiffs' own idiosyncratic reactions, and/or by operation of nature.

33. Plaintiffs' claims are barred on the grounds that plaintiffs knew, or in the exercise of ordinary care should have known, of the risks of the injuries or damages alleged in the FAC, if any, and nevertheless, did freely and voluntarily assume said risks, and in this undertaking proximately caused and contributed to the losses, injuries, or damage, if any, alleged by plaintiffs.

34. Plaintiffs' claims against Mutual are barred by the learned intermediary doctrine.

35. Plaintiffs are barred, in whole or in part, from recovery due to spoliation of evidence.

36. There is no responsibility for either the acts or omissions of the knowledgeable users or misinformation or lack of information provided to the plaintiffs by others.

37. With respect to each and every cause of action, plaintiffs are not entitled to recover because of the delay and the fundamental unfairness and prejudice due to the excessive delay from the date of the alleged use of the products allegedly sold by Mutual and the filing of the FAC.

38. There were no warranties, either express or implied, between plaintiffs and Mutual.

39. Mutual breached no warranties, either express or implied, which may have existed between it and plaintiffs.

40. Plaintiffs failed to give notice of any alleged breach of any warranty as required by state law and is, therefore, barred from any recovery for such claims.

41. The express and implied warranties alleged to have been made were expressly disclaimed and

excluded by the label; any and all statements made concerning the product referred to in the FAC applied only when used as directed.

42. To the extent plaintiffs seek exemplary or punitive damages, the Complaint fails to allege facts sufficient to entitle plaintiffs to an award of exemplary or punitive damages.

43 To the extent plaintiffs seek exemplary or punitive damages, such damages are prohibited under the Fifth, Eighth, and Fourteenth Amendments of the United States Constitution and are limited or barred by New Hampshire law.

44. To the extent plaintiffs seek exemplary or punitive damages, such damages are prohibited under New Hampshire law, N.H.R.S.A. Sec. 507:16.

45. To the extent plaintiffs seek exemplary or punitive damages, Mutual specifically incorporates by reference all standards and/or limitations regarding the determination and enforceability of punitive damage awards which arise in the decisions of *BMW of North America v. Gore,* 517 U.S. 559 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), and *State Farm Mut. Auto. Ins. Co. v. Campbell,* 123 S. Ct. 1513, 1519, 1521 (2003).

46. To the extent that the claims stated in the Complaint have been settled, compromised, or otherwise discharged, a set off is due.

47. Plaintiffs fail to state a claim upon which attorneys' fees can be awarded.

48. Mutual adopts and relies upon all provisions and defenses afforded it under Restatement of Torts 2d, § 402A, including the comments thereto.

49. Mutual reserves the right to raise all defenses provided in sections 2, 4, and 6 of the Restatement (Third) of Torts: Product Liability, if the Court finds that it is applicable in this case.

50. Mutual incorporates all defenses available under New Hampshire's liability law.

51. Plaintiffs' claims, if any, are barred, reduced and/or limited pursuant to any other applicable limitations of awards, caps on recovery, and setoffs permitted by law, including, but not limited to New Hampshire law regarding noneconomic loss or injury, and applicable New Hampshire law related to amounts paid or provided by collateral sources.

52. Mutual adopts and relies upon all provisions and defenses afforded it under the United States Constitution and the New Hampshire Constitution.

53. The product that is at issue in this litigation was not in an unreasonably dangerous condition.

54. Mutual's conduct was not the proximate or producing cause of plaintiffs' alleged injuries, if any.

55. Mutual's product was not defective in manufacture, design, construction, or formulation, and it conformed to all representations made by Mutual, if any.

56. If plaintiffs suffered or sustained any injuries, loss, or damage as a result of the alleged incident referred to in the FAC, the same were a direct result of plaintiffs' failure to follow the reasonable advice of her health care providers.

57. The injuries or damages sustained by plaintiffs, if any, may be attributed to several causes and

accordingly should be apportioned among the various causes according to the respective contribution of each such cause to the harm sustained.

58. Plaintiffs failed to exercise ordinary care under the circumstances in using the product and such failure was the substantial cause of the occurrence that caused injury or damage, if any, to plaintiffs.

59. Plaintiffs' claims are barred by additional defenses that may arise during the course of this litigation, which Mutual reserves the right to assert.

60. Mutual incorporates the defenses of all others who are or may become parties to this action as though more fully set forth herein.

JURY DEMAND

A TRIAL BY JURY IS DEMANDED.

/s/ Paul J. Cosgrove
Pro hac vice
Joseph P. Thomas
(OH Bar No. 0040379)
Pro hac vice
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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the above and foregoing instrument was served upon the following counsel of record via electronic case filing this 8th day of February, 2010.

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/s/ Paul J. Cosgrove

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett
and Gregory S. Bartlett

v. Civil No. 08-cv-358-JL
Opinion No. 2009 DNH 166

Mutual Pharmaceutical
Company, Inc., et al.

MEMORANDUM ORDER

Plaintiffs have filed a motion for sanctions under Rule 37 of the Federal Rules of Civil Procedure in response to the defendant Mutual Pharmaceutical Company's belated production of certain documents. After reviewing the parties' written submissions and hearing oral argument, this court grants the motion in part and denies it in part. As explained below, Mutual lacked a substantial justification for failing to produce the documents in a timely manner and is therefore subject to sanctions. Because Mutual acted in good faith, however, the court allows only some of the relief that the plaintiffs have requested.

I. Applicable legal standard

Rule 37 provides for discovery sanctions in a number of different situations, two of which the plaintiffs invoke here. The first is when a party "fails to obey an order to provide or permit discovery." Fed. R. Civ. P 37(b)(2)(A). As its plain language suggests, Rule 37(b) requires the moving party to establish "two things as conditions precedent to engaging the gears of the rule's sanction machinery: a court order must be in effect, and then must be violated." Ortiz-Lopez v. Socieded Espanola de Auxilio Mutuo & Benefiencia de

P.R., 248 F.3d 29, 33 (1st Cir. 2001) (quoting R.W. Int'l Corp. v. Welch Foods, Inc., 937 F.2d 11, 15 (1st Cir. 1991)).

The second situation is when a party fails to supplement its discovery responses, as required by Rule 26(e), upon learning that its earlier production is materially incomplete or incorrect. Fed. R. Civ. P. 37(c)(1). Unlike the first situation, no court order needs to be in place for the imposition of Rule 37(c) sanctions. See Ortiz-Lopez, 248 F.2d at 33; Thibeault v. Square D Co., 960 F.2d 239, 245 (1st Cir. 1992). Rather, once the moving party has shown a violation of Rule 26(e), the party facing sanctions for belated disclosure has the obligation to show that its failure to comply with the rule was either "substantially justified" or "harmless." Fed. R. Civ. P. 37(c)(1); Wilson v. Bradlees of New Eng., Inc., 250 F.3d 10, 21 (1st Cir. 2001).

II. Background

This court recently summarized the plaintiffs' allegations as follows:

> In December 2004, Karen Bartlett's physician prescribed her Sulindac, a non-steroidal anti-inflammatory drug manufactured by the defendants, for pain in her right shoulder. Within weeks of filling the prescription, she went to a local emergency room complaining of "pimple like bumps, spots or blisters on her face, a fever, eye irritation," and other symptoms. She was soon diagnosed with Stevens-Johnson syndrome progressing to toxic epidermal necrolysis, a serious and potentially fatal condition characterized by large areas of lesions on and necrosis of the skin and mucous membranes. See Dorland's Illustrated Medical Dictionary 1872 (31st ed. 2007). She spent

> approximately three months in the hospital recovering, including two months in a medically induced coma, and emerged with permanent injuries.
>
> Sulindac is the generic version of a drug originally approved by the FDA in 1978; the generic version at issue here was approved in 1991. The Bartletts allege that, following this approval, the defendants "had an ongoing duty to conduct postmarketing safety surveillance for any reports of serious adverse events associated with Sulindac including any such report in the medical literature" and that, had they done so, they would have uncovered information compelling them "to warn physicians about the dangers" of the drug, including associations with Stevens-Johnson syndrome and toxic epidermal necrolysis.

Bartlett v. Mut. Pharm. Co., ___ F. Supp. 2d ___, 2009 DNH 144, 3-5 (denying defendants' motion for judgment on the pleadings).

During discovery, the Bartletts requested that Mutual produce "[a]ny and all Annual and Periodic Reports filed by [defendants] for any Sulindac products." Federal regulations require companies that hold applications for new drug approval (known as "ANDAs" and "NDAs") to file periodic reports with the Food & Drug Administration ("FDA") describing any adverse event information relating to those drugs, see 21 C.F.R. § 314.80(c)(2), and also to file annual reports that summarize any "significant new information" that might affect the drug's "safety, effectiveness, or labeling." See id. § 314.81(b)(2)(i). Reports that reflect adverse event information must be retained by the ANDA holder for at least ten years. See id. § 314.80(i).

Since Mutual has held an ANDA for Sulindac since 1991, the Bartletts expected to receive at least a decade's worth of annual and periodic reports in discovery. Mutual, however, produced only three periodic reports (from 2001-02 and 2008) and no annual reports.

Shortly after this production, on January 2, 2009, the parties held a court-ordered telephone conference to address unresolved discovery issues.[1] During the conference, Mutual's counsel stated that "we already produced" all annual and periodic reports and that an affidavit to this effect would be forthcoming. The affidavit, signed on January 21, 2009 by Mutual's Vice President of Regulatory Affairs, Robert Dettery, stated: "Following reasonable inquiry, Mutual has produced all adverse event related documents in its possession regarding [S]ulindac, including ... periodic reports."

On August 14, 2009, one month before the scheduled close of discovery, plaintiffs' counsel mentioned to Mutual's counsel that they had been unable to locate all of the annual and periodic reports in Mutual's production. Mutual's counsel replied that "you have everything there is." But on August 28, 2009, in connection with Dettery's deposition, Mutual's counsel learned that this statement had been incorrect and that additional annual and periodic reports existed

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[1] The relevant order stated "the court will likely assess fees and costs against the parties and/or counsel for any discovery disputes with respect to which their positions are deemed unreasonable or not well supported by applicable law." Document no. 48. About a month later, in advance of a hearing on plaintiffs' motion to compel discovery, this court again stated in a margin order that "positions deemed unreasonable by the court at the hearing will result in commensurate awards of attorneys' fees and costs."

in Mutual's off-site storage, unknown to Dettery but known to his subordinate Andria Werynski, Mutual's Manager of Regulatory Affairs, who had helped with the initial production of the three periodic reports.

Mutual produced the additional periodic reports on September 1, 2009 and the additional annual reports on September 8, 2009, one week before the scheduled close of discovery and plaintiffs' expert disclosure deadline. The reports totaled 4277 pages -- more than Mutual's entire production up to that point (3687 pages). As it turned out, none of them reported any adverse events. The only three reports with adverse event information were the ones that Mutual had produced earlier in the case. Notwithstanding the late production, plaintiffs managed to review the additional reports, forward them to their experts to consider, and meet their expert disclosure deadline.

Plaintiffs now request discovery sanctions under Rule 37. Specifically, the plaintiffs have requested that the court (a) exclude the reports from evidence; (b) allow plaintiffs to conduct an on-site inspection for additional responsive documents in Mutual's possession; and (c) award attorneys' fees and costs caused by the discovery error.[2]

---

[2] In the event that such relief is denied, plaintiffs alternatively request the opportunity to conduct discovery of the facts underlying Mutual's late production. In light of the other relief granted in this order, the court need not reach -- and, in any event, declines to grant -- this alternative request. The court sees little value in conducting such discovery at this point, particularly after the extensive discussion of the underlying facts at oral argument.

III. Analysis

Plaintiffs have invoked two separate grounds for imposing Rule 37 sanctions on Mutual: failure to comply with a discovery order under Rule 37(b) and failure to supplement discovery under Rule 37(c). As explained below, Mutual has not violated a specific discovery order and thus cannot be sanctioned under Rule 37(b). Nevertheless, Mutual failed to supplement its document production, which was neither substantially justified nor harmless, and is therefore subject to sanctions under Rule 37(c). Because Mutual acted in good faith, however, the court grants only some of the relief requested by plaintiffs.

A. *Rule 37(b)*

Plaintiffs have not established either of the two prerequisites for discovery sanctions under Rule 37(b): first, that the court issued an applicable discovery order; and second, that the defendants violated it. See Ortiz-Lopez, 248 F.3d at 33. Plaintiffs point to two general orders from this court warning the parties not to take unreasonable positions in discovery. See note 1, supra. But neither order mentions plaintiffs' request for annual and periodic reports, or even the completeness of the defendants' document production. "The proposition that an order to answer specific [discovery requests] can be implied from such a blanket directive -- a directive which does not mention the subject matter inquired into -- is inconsistent with both the structure and language of Rule 37." R.W. Int'l Corp., 937 F.2d at 16. Accordingly, this court cannot grant discovery sanctions under Rule 37(b).[3]

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[3] At oral argument, plaintiffs' counsel appeared to concede this point.

B. *Rule 37(c)*

Rule 37(c) authorizes discovery sanctions when a party fails to supplement its discovery responses as required by Rule 26(e), "unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1); see also Ortiz-Lopez, 248 F.2d at 33. Rule 26(e), in turn, requires a party who has responded to a request for production to supplement or correct its response "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect." Fed. R. Civ. P 26(e)(1). The court of appeals has said that Rule 37(c) "clearly contemplates stricter adherence to discovery requirements, and harsher sanctions for breaches." Gagnon v. Teledyne Princeton, Inc., 437 F.3d 188, 191 (1st Cir. 2006) (quotation omitted).

As an initial matter, Mutual argues that it complied with Rule 26(e) because it supplemented its production with the missing reports as soon as possible after learning that its earlier production had been incomplete -- and still met the discovery deadline. The court disagrees. Mutual has conceded that its Manager of Regulatory Affairs (Werynski) knew all along about the off-site storage of the reports, even if Mutual's counsel and its Vice President of Regulatory Affairs (Dettery) did not. Werynski helped with Mutual's earlier production of three periodic reports and easily could have been, but was not, asked to retrieve the rest of the reports. Under basic agency principles, her knowledge can be imputed to Mutual for purposes of Rule 26(e). Moreover, there is some authority for the proposition that Rule 26(e) requires a party to turn over not only responsive documents of which it is actually aware, but also documents of which it

reasonably should be aware. See 7 James Wm. Moore et al., Moore's Federal Practice § 26.131[3] (3d ed. 2009) (citing Arthur v. Atkinson Freight Lines Corp., 164 F.R.D. 19, 20 (S.D.N.Y. 1995)); but see Zubulake v. UBS Warburg LLC, 229 F.R.D. 422, 433 (S.D.N.Y. 2004) (requiring "actual knowledge") (quoting F.R.C.P. 26(e), advisory committee notes (1970)). Regardless of which standard applies, Mutual both knew and should have known about the off-site reports and thus had a duty to supplement its production under Rule 26(e).

As to the timing of the additional production, Rule 26(e) requires supplementation in a "timely manner." Mutual produced the additional reports eight months after expressly representing to the plaintiffs that all such reports had been produced. This production, while made just before the discovery deadline, was not timely. Mutual objects that the plaintiffs also waited eight months before raising concerns about the missing reports. But the duty to supplement under Rule 26(e) does not depend upon repeated requests by an adversary for updated or complete information. See AVX Corp. v. Cabot Corp., 252 F.R.D. 70, 77 (D. Mass. 2008) (citing Arthur, 164 F.R.D. at 20, and Moore, supra, at § 26.131[3]). This court therefore finds that Mutual violated Rule 26(e).

Mutual has not shown a substantial justification for its late production of the reports. Plaintiffs made a very specific request for them, which the parties expressly discussed at a court-ordered conference. Unlike a broad request for all documents relating to a given topic, which can present a complex challenge for document collection and review, this request targeted a discrete and easily identifiable set of formal FDA filings. They are standard fare for discovery in

pharmaceutical litigation of this sort. Given that Mutual made a fairly small document production (less than 4000 pages) that included only three periodic reports, the absence of the remaining periodic reports and all of the annual reports (which together exceed 4000 pages) was glaring and should have caused Mutual and its counsel to take the reasonable steps necessary to locate them. See Sheppard v. River Valley Fitness One, L.P., 428 F.3d 1, 12 (1st Cir. 2005) (stating that the phrase "substantially justified" under Rule 37 means "justified to a degree that could satisfy a reasonable person") (quoting Pierce v. Underwood, 487 U.S. 552, 565 (1988)).

Mutual claims that it failed to notice the omission because the production, which it made electronically, included a folder entitled "ANDA & FDA Correspondence." The ANDA, it says, is a living document that ordinarily would include all annual and periodic reports filed with the FDA to date. At oral argument, Mutual conceded that if someone familiar with ANDAs had reviewed the electronic folder, he or she would have known that parts of the ANDA were missing. The only person who reviewed the folder before production, however, appears to have been a paralegal checking for privilege and confidentiality (not content). This court recognizes that today's electronic productions tend to be larger and less tangible than paper productions in the past, potentially making it harder to notice omissions. But in this case, Mutual's entire production totaled less than 4000 pages, which -- regardless of format -- would not have taken long to review.[4] Mutual was not substantially justified in

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4 Indeed, after catching the mistake and retrieving the additional reports, Mutual's counsel apparently took the time to

assuming that the ANDA folder contained all of the annual and periodic reports, without making a reasonable effort to verify its contents. See, e.g., Gagnon, 437 F.3d at 196 (finding no substantial justification where party did not satisfy its "obligation to investigate" the discovery issue).

Mutual also emphasizes that its senior regulatory affairs executive simply made a good-faith mistake, believing that the reports had been destroyed until he learned from a subordinate that they were actually being stored off-site. The court takes Mutual at its word. Nevertheless, even good-faith mistakes can lack a substantial justification and thus be sanctionable under Rule 37(c). See, e.g., Thibeault, 960 F.2d at 245 (mentioning "laxity" as an example). This court rejects the notion that a senior executive's belief that certain documents have been destroyed -- without personal knowledge and without consulting the employees most familiar with such documents -- relieves a company of its obligation to search any further. Here, Mutual's failure to produce the additional reports until a week before the close of discovery, despite the plaintiffs' straightforward document request and Mutual's express representation that the reports had already been produced months earlier, was not substantially justified. See Primus v. United States, 389 F.3d 231, 235 (1st Cir. 2004) (affirming Rule 37(c) sanctions where the district court "considered, but was unimpressed with, [the party's] explanations for her tardiness").

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review them all before production, which occurred in a matter of days. See Document no. 64, at 7 n.7.

Nor can Mutual's discovery error be called harmless. The Bartletts proceeded for eight months in reliance on Mutual's false representations that all annual and periodic reports in its possession had been produced. Indeed, the Bartletts were planning to seek a spoliation instruction at trial that would allow the jury to infer that the missing reports contained adverse event information. They prepared to -- and did -- ask about the reports in multiple depositions of Mutual employees, hoping to lay the groundwork for such an instruction. Mutual's late production negated this trial strategy and the efforts devoted to it. Moreover, by the time the reports were finally produced, the Bartletts' expert disclosure deadline was only a week away. Thus, whether or not the experts ultimately referred to or relied on the new information, it had to be reviewed, analyzed, and factored into their expert disclosures on an expedited basis. These efforts may not have been devastating to the Bartletts' case, but neither were they harmless. See Primus, 389 F.3d at 236 (finding sanctions justified where "real resources were expended on legal work that was premised on" the discovery error); Gagnon, 437 F.3d at 197 (calling harmlessness "a fairly limited concept" and "the smaller escape valve in Rule 37(c)(1)"). Mutual's discovery error is therefore sanctionable under Rule 37(c).

C. *Appropriate relief*

This court has broad discretion under Rule 37(c) to "fashion an appropriate sanction from a wide range of options." Thibeault, 960 F.2d at 245; see also LaPlace-Bayard v. Batlle, 295 F.3d 157, 162 (1st Cir. 2002). These options include striking the documents from evidence, ordering payment of reasonable attorney's

fees and expenses caused by the discovery error, informing the jury of the error, or imposing any "other appropriate sanctions." Fed. R. Civ. P. 37(c)(1)(A)-(C). As the court of appeals has explained, "[t]he range of sanctions provided in Rule 37(c) ... gives the district court leeway to best match the degree of non-compliance with the purpose of Rule 26's mandatory disclosure requirements." Ortiz-Lopez, 248 F.3d at 34 (citing Poulin v. Greer, 18 F.3d 979, 984 (1st Cir. 1994)). In choosing the appropriate sanction, the court may consider a variety of factors, including the reason for the error, whether the party made it in good faith, the history of the litigation, the significance of the documents, the prejudice caused by the error, the other party's ability to overcome it, and the need to deter other litigants from disregarding procedural rules. See, e.g., Santiago-Diaz v. Laboratorio Clinico & de Referencia del Este, 456 F.3d 272, 276-77 (1st Cir. 2006); Gagnon, 437 F.3d at 199; Thibeault, 960 F.2d at 245 & n.4.

The most common sanction for Rule 37(c) violations, and the first one that the Bartletts request, is the exclusion from evidence of the relevant documents. See, e.g., Lohnes v. Level 3 Commc'ns, Inc., 272 F.3d 49, 60 (1st Cir. 2001). For more serious violations, this sanction is "near automatic." Wilson, 250 F.3d at 20. Where appropriate, however, the rule also expressly allows a court to impose other relief "instead of this sanction." Fed. R. Civ. P. 37(c) (emphasis added); see also Santiago-Diaz, 456 F.3d at 276 (confirming that "district courts have some discretion in deciding whether or not to impose that onerous sanction") (citing Jackson v. Harvard Univ., 900 F.2d 464, 468-69 (1st Cir. 1990)). In this case, the court considers exclusion to be an inappropriate remedy for a variety of

reasons. First, Mutual made the discovery error in good faith, without any intent to disregard the procedural rules. Second, it is unclear which party would benefit more from the inclusion or exclusion of the reports.[5] Third, the plaintiffs already managed to review the documents and factor them into their expert disclosures, albeit under unnecessary time pressure, and will not be unfairly prejudiced by their inclusion in evidence going forward. In contrast, excluding the documents could leave an unexplained and potentially confusing gap in the evidentiary record at trial. See Jackson, 900 F.2d at 469 (declining to impose exclusion sanction where it would "serve[ ] only further to suppress evidence" and would not be "appropriate to the truth-finding process"). For all these reasons, the court declines to exclude the reports from evidence.

Next, the Bartletts request an opportunity to conduct an on- site inspection of Mutual's computer systems; searching for emails and other documents that reflect adverse event information relating to Sulindac and four other drugs manufactured by Mutual (ibuprofen, tolmetin, indomethacin, and Bactrim). The purpose of this inspection, they say, would be to provide independent confirmation that Mutual's production has been comprehensive.

Plaintiffs acknowledge that they have not targeted the four additional drugs in their prior discovery

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[5] On one hand, the reports do not identify any adverse event information relating to Sulindac, making them potentially beneficial to Mutual. On the other hand, the Bartletts (despite requesting their exclusion from evidence) go so far as to call the reports "incriminatory" of Mutual in that they "demonstrate violations of the code of federal regulations." Exclusion is less likely to be an effective remedy in these circumstances. See Fed. R. Civ. P. 37(c), advisory committee notes (1993).

requests, but claim that recent depositions have given them reason to believe that Mutual might have learned about Sulindac's adverse effects in connection with those other drugs.

This court agrees that Mutual's late production of the annual and periodic reports, which exceeded the size of its entire original production, raises concerns about whether its production has been thorough. At the same time, the court takes Mutual at its word that it has made the production in good faith. On balance, the court finds that some "double-checking" of Mutual's production is necessary and appropriate, but that it can be conducted by Mutual and its counsel rather than by plaintiffs and their counsel, which will help to mitigate any countervailing concerns raised by Mutual about the handling of privileged materials.

As to the four additional drugs, the court considers it fair and fitting, given how long it took Mutual to produce the Sulindac reports, to allow some additional discovery at this stage by the Bartletts. They bore the burdens of Mutual's late production, and so deserve the benefits as well. Their requested discovery seems reasonably calculated to lead to the discovery of admissible evidence and, moreover, should help to confirm whether Mutual's production as to Sulindac and its adverse effects has been comprehensive. Under the circumstances, such relief is the "best match" for Mutual's discovery error. Ortiz-Lopez, 248 F.3d at 34; cf. Jackson, 900 F.2d at 469 (deeming "further discovery" to be an appropriate "response to the problems created by [a party's] negligence").[6]

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[6] The court notes that it could allow such relief even in the absence of a Rule 37(c) violation, under its inherent authority to regulate the discovery process, and, in the alternative, orders the

The court therefore orders Mutual to conduct a reasonable review and to confirm, in a writing submitted to this court within 45 days of this order, that it has produced to the plaintiffs all documents (including emails) in its possession, custody, or control that relate to Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms, erythema multiforme, or other serious skin reactions, in connection with any of the following five drugs: Sulindac, ibuprofen, tolmetin, indomethacin, and Bactrim (both branded and generic).

Finally, the Bartletts seek reimbursement from Mutual of their attorneys' fees and costs caused by Mutual's discovery error. The court of appeals has called this one of the "more moderate" sanctions available under Rule 37(c). Id. at 34. This court considers such an award necessary and appropriate here, given the harm that Mutual's error caused, the lack of substantial justification for the error, and the other considerations discussed above. The court therefore orders Mutual to reimburse the plaintiffs for their reasonable attorneys' fees and costs caused by the late production of the annual and periodic reports, including fees and costs associated with litigating the motion for sanctions. In light of the good- faith nature of Mutual's error, however, the court strongly cautions the plaintiffs to avoid any over-reaching as to the amount of fees and costs requested. All such fees and

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production on that basis. See, e.g., Vineberg v. Bissonnette, 548 F.3d 50, 54-55 (1st Cir. 2008); U.S. v. Sayer, 450 F.3d 82, 89-90 (1st Cir. 2006); Williams v. Monarch Mach. Tool Co., 26 F.3d 228, 230 (1st Cir. 1994). Discovery is still underway at this point, thanks in part to Mutual's successful push, over the Bartletts' objection, for an extension of the discovery and trial schedule.

costs should be substantiated and clearly attributable to Mutual's late production.

IV. Conclusion

For the foregoing reasons, plaintiffs' motion for sanctions[7] is GRANTED as to parts (b) and (c), subject to the limitations set forth in this order, and otherwise DENIED as to parts (a), (d), and (e). Mutual shall submit to this court within 45 days of this order a written confirmation that it has conducted the review and document production ordered by Part III.C, infra. In addition, if the parties cannot agree on a reasonable amount of attorneys' fees and costs, see id., plaintiffs shall submit to the court, within 14 days of this order, an itemized bill, with the opportunity for Mutual to respond within 14 days of such filing.

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: November 2, 2009

cc: Bryan Ballew, Esq.
Keith M. Jensen, Esq.
Christine M. Craig, Esq.
Timothy P Beaupre, Esq.
Patrick J. O'Neal, Esq.
Paul J. Cosgrove, Esq.
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Linda E. Maichl, Esq.
Stephen J. Judge, Esq.

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[7] Document no. 67.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen S. Bartlett

v. Civil No. 08-cv-00358-JL

Mutual Pharmaceutical Company, Inc.

ORDER

The plaintiff's "Motion to Strike Defense Expert Dr. Stern and Related Relief" (document no. 230) is granted in part. Given the significance of the recently discovered manuscript and the failure to disclose it in a timely manner, Mutual shall make Drs. Stern and Valuck available for a supplemental deposition, to be conducted as soon as possible and not to exceed two hours each. See Fed. R. Civ. P. 37(c)(1)(C). Bartlett is granted leave to add the manuscript to her exhibit list and expert reliance materials. She may also request a jury instruction regarding the late production. See Fed. R. Civ. P. 37(c)(1)(B). All other requested relief is denied as inappropriate under the circumstances.

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: July 16, 2010

cc: Keith M. Jensen, Esq.
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Paul J. Cosgrove, Esq.
Stephen J. Judge, Esq.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW HAMPSHIRE

KAREN L. BARTLETT
and
GREGORY S. BARTLETT,
Plaintiffs,
vs.
MUTUAL PHARMACEUTICAL COMPANY, INC., et al., Defendants.

Case No. 08-cv-358-JL
Judge Joseph N. Laplante

DEFENDANT'S REQUESTED JURY INSTRUCTIONS

Defendant Mutual Pharmaceutical Company, Inc., by and through its undersigned counsel hereby submits its requested jury instructions and verdict form. Defendant reserves the right to amend and/or supplement its proposed instructions and verdict form following the Court's rulings on pending motions and rulings made by the Court during the trial. In addition, Mutual expressly reserves its right to file supplemental requests for jury instruction at the close of the evidence or at such earlier time during trial as the Court reasonably directs, as expressly provided by L.R. 16.2(b)(1).

Respectfully submitted,

/s/ Paul J. Cosgrove
Paul J. Cosgrove

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PRELIMINARY STATEMENT REGARDING REQUESTED JURY INSTRUCTIONS

Pursuant to Local Rule 16.2(b)(1), Mutual acknowledges the directive that jury instructions such as "the role of the jury, evaluating witness credibility, burden of proof, and other instructions routinely given by the court are not to be included in the proposed jury instructions." For the record, Mutual requests the Court provide instructions on the following topics[8]:

Preamble to Instructions

Equality of the Parties – Individuals and Corporations

Sympathy, Prejudice, Fear, or Favor to Be Avoided

Evidence Defined

Jury to Consider All the Evidence

Law From the Court

Inadmissible and Stricken Evidence

Credibility of Witnesses

Expert Witnesses

Preponderance of Evidence

Fact of Incident Not Evidence of Liability

Legal Fault

Damages – Closing Argument

Loss of Earning Capacity

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[8] Mutual will submit proposed jury instructions on these issues should the Court request same.

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 1

Strict liability - Defective Design

In order for Ms. Bartlett to recover for her injury for a defect in the design of Mutual's sulindac under a strict liability theory, she must prove by the greater weight of the evidence all the following:

1. Ms. Bartlett took a generic pharmaceutical product manufactured by Mutual containing the active ingredient sulindac and normal binders and fillers; and

2. The generic pharmaceutical product Ms. Bartlett took had a defect because the product contained an additional ingredient, other than sulindac and the normal binders and fillers in the product, that the ordinary consumer would not have expected to be in the product; and

3. The additional ingredient, and not the sulindac or normal binders and fillers in the product, made the product defective; and

4. The defective condition of Mutual's pharmaceutical product rendered it unreasonably dangerous; and

5. The use of the product was reasonably foreseeable by Mutual; and

6. Dr. Ergin was unaware of the dangers and risks associated with Mutual's pharmaceutical product; and

7. The defective condition of Mutual's pharmaceutical product was a legal cause of the injury to Ms. Bartlett.

(*See* Restatement (Second) of Torts, § 402A *Cmt i* (1969); *Buckingham v. R.J. Reynolds Tobacco Co.*, 142 N.H. 822, 713 A.2d 381 (1998).)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 2

Negligence - Defective Design

In order for Ms. Bartlett to recover for her injury for a defect in the design of Mutual's sulindac under a negligence theory, the greater weight of the evidence must show the following:

1. That Mutual designed sulindac; and

2. That Mutual did not act as a reasonably prudent manufacturer in designing sulindac; and

3. Ms. Bartlett took a generic pharmaceutical product manufactured by Mutual containing the active ingredient sulindac and the normal binders and fillers; and

4. The generic pharmaceutical product Ms. Bartlett took had a defect because the product contained an additional ingredient, other than sulindac and the normal binders and fillers, that the ordinary consumer would not have expected to be in the product; and

5. The additional ingredient, and not the sulindac or the normal binders and fillers, made the product defective; and

6. The defective condition of Mutual's pharmaceutical product rendered it unreasonably dangerous; and

7. The use of the product was reasonably foreseeable by Mutual; and

8. Dr. Ergin was unaware of the dangers and risks associated with Mutual's pharmaceutical product; and

9. The defective condition of Mutual's pharmaceutical product was a legal cause of the injury to Ms. Bartlett.

(New Hampshire Civil Jury Instruction 6.1, as modified.)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 3

Negligence Defined – Design Defect

Negligence is the failure to use reasonable care. Reasonable care is the degree of care which an ordinary, prudent generic drug manufacturer would exercise under the same or similar circumstances in the design of a generic pharmaceutical product. The failure to exercise reasonable care may take the form of action or inaction. That is, negligence may consist of either: doing something that an ordinary, prudent generic drug manufacturer would do under the same or similar circumstances; or, failing to do something that an ordinary, prudent generic drug manufacturer would do under the same or similar circumstances.

The duty to use reasonable care arises from the risk to others which could be reasonably foreseen. Thus, Mutual may not be found negligent in the design of sulindac if it could not reasonably foresee that its conduct would result in an injury to another, or if its conduct was reasonable in light of the anticipated risks. Also bear in mind that a person or entity has no duty to anticipate the careless conduct of another.

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 4

Design Defect – Defect Defined

A defect in design occurs when the product sold has been manufactured in conformity with the manufacturer's design, but the design itself presents unreasonable dangers to users.

A defect in the design of a pharmaceutical product requires that the product contain an additional ingredient which the ordinary consumer would not expect to be present in the product. Pharmaceutical products that do not contain an additional ingredient the ordinary consumer would not expect are not defective as a matter of law. If you cannot find such an additional ingredient in this case – in other words, if Mutual's pharmaceutical product contained only sulindac and the necessary binders and fillers found in a prescription drug tablet, you must find for the defendant.

(New Hampshire Civil Jury Instruction 23.3, as modified; Restatement (Second) of Torts, § 402A *Cmt i* (1969).)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 5

Design Defect – Manufacturer Does Not Have a Duty to Design the Safest Product

A manufacturer is not obliged to design the safest possible product, or a safer product, or one as safe as others make, so long as the design does not contain a defect that makes it unreasonably dangerous.

(*Thibault v. Sears, Roebuck & Co.*, 118 N.H. 802 (1978).)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 6

Unreasonably Dangerous – Factors to Consider

It is not sufficient for Ms. Bartlett to prove that a product is unreasonably dangerous. She must prove that the product contained a defect in its design and that the defect caused the product to be unreasonably dangerous. Accordingly, you will not decide whether Mutual's sulindac is unreasonably dangerous unless you first have decided that it is defective in design.

In order to prove that a defective design presents an unreasonable danger, Ms. Bartlett must present evidence from which you can assess the desirability and usefulness of the product to the public as a whole. In weighing utility and desirability against danger, you should consider whether the risk of danger could have been reduced without a significant impact on product effectiveness and manufacturing cost.

(*Buckingham v. R.J. Reynolds Tobacco Co.*, 142 N.H. 822, 713 A.2d 381 (1998); *Thibault v. Sears, Roebuck & Co.*, 118 N.H. 802 (1978).)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 7

Unavoidably Unsafe

Only if you determine Mutual's sulindac was defective and that it was unreasonably dangerous, will you consider whether it was unavoidably unsafe.

Some products are so important that a manufacturer may avoid liability as a matter of law if the manufacturer has given proper warnings. In order to avail itself of this defense, ordinarily, Mutual must prove by the weight of the evidence that the warning it provided to Dr. Ergin was proper. In deciding whether the warning was proper, you should assess whether, through its warning, Mutual took available and reasonable steps to advise physicians of the risks associated with the product. Mutual is not required to provide the best warning, or even a better warning than some other manufacturer. Rather, Mutual is required to provide only a warning that was reasonable under the circumstances.

You may determine from the evidence that Dr. Ergin did not read the warning provided by Mutual. If you find that Mutual's sulindac was unavoidably unsafe and that Dr. Ergin did not read the warning for Mutual's sulindac, you must find for Mutual because a failure to provide a reasonable warning cannot be a cause of plaintiff's injuries. Accordingly, if Mutual's sulindac was unavoidably unsafe, Mutual may avoid liability as a matter of law if it has given reasonable warnings of dangers incident to use of sulindac, or regardless of whether the warnings were reasonable, if Dr. Ergin did not read the warnings.

In considering any warning you believe Mutual should have provided, you must consider that Mutual need not warn of a one-in-a-million chance of injury. Nor is Mutual required to warn against dangerous uses which are not intended and not reasonably foreseeable by it. Individual users do have certain responsibilities. Mutual cannot reasonably foresee and warn of every conceivable danger of its product.

If you find that Mutual's product was unavoidably unsafe and that Mutual's warning was adequate or that Dr. Ergin did not read it, you must find for Mutual, even if you determine that its sulindac was defective and unreasonably dangerous.

(New Hampshire Civil Jury Instruction 23.4, in part; *Thibault v. Sears, Roebuck & Co.*, 118 N.H. 802 (1978); Restatement (Second) of Torts, § 402A *Cmt k*; Court's)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 8

Negligence of Dr. Ergin

If you determine that a defect existed in Mutual's sulindac and that defect caused it to be unreasonably dangerous, and you find Mutual liable, you also are to determine whether Dr. Ergin was negligent.

Negligence

Negligence is the failure to use reasonable care. Reasonable care is the degree of care which an ordinary, prudent doctor would exercise under the same or similar circumstances. The failure to exercise reasonable care may take the form of action or inaction. That is, negligence may consist of either: doing something that an ordinary, prudent doctor would do under the same or similar circumstances; or, failing to do something that an ordinary, prudent doctor would do under the same or similar circumstances.

The duty to use reasonable care arises from the risk to others which could be reasonably foreseen. Thus, Dr. Ergin may not be found negligent if he could not reasonably foresee that his conduct would result in an injury to another, or if his conduct was reasonable in light of the anticipated risks. Also bear in mind that a person has no duty to anticipate the careless conduct of another.

Legal Cause

Failure to exercise reasonable care amounts to legal fault if you find that such failure was a legal cause of the incident and injury. When is negligence a legal cause of harm? When the negligent conduct is a substantial factor in bringing about the harm, and if

the harm would not have occurred without that conduct.

On the other hand, if negligent conduct is not a substantial factor in bringing about the harm, it cannot be the basis for a finding of legal harm.

In determining whether Dr. Ergin's conduct was a legal cause of Ms. Bartlett's injury, you need not find that Dr. Ergin's conduct was the sole cause of the injury. You need only find that it was a substantial factor in bringing about the injury, even though other factors also may have contributed to cause the injury.

Summary

To summarize – If you find Dr. Ergin was negligent, any recovery against Mutual will be reduced. Mutual must prove Dr. Ergin's negligence and harm and that they have a direct, causal connection to plaintiff's injury. Again, the negligence need not be the only cause of the injury, but it must be a substantial factor in bringing about the injury. In such a case, plaintiff's recovery against Mutual, if any, will be reduced based upon Dr. Ergin's negligence.

New Hampshire Civil Jury Instructions 6.1 and 13.1, in part.

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 9

Learned Intermediary

Dr. Ergin was aware of the risk of SJS and TEN from sulindac at the time he prescribed it to plaintiff. As a result if you find that Mutual's sulindac was unavoidably unsafe, you must find for Mutual because a failure to provide a reasonable warning cannot have been a cause of plaintiff's injuries. Accordingly, if Mutual's sulindac was unavoidably unsafe, Mutual may avoid liability as a matter of law if it has given reasonable warnings of dangers incident to use of sulindac, or regardless of whether the warnings were reasonable, if Dr. Ergin was aware of the risk of SJS and TEN at the time he prescribed it to plaintiff.

If you find that Mutual's product was unavoidably unsafe and that Mutual's warning was adequate or that Dr. Ergin was aware of the risk of SJS and TEN at the time he prescribed it to plaintiff, you must find for Mutual, even if you determine that its sulindac was defective and unreasonably dangerous.

See Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 656 (1st Cir. 1981); *McCue v. Norwich Pharmacal Co.*, 453 F.2d 1033, 1035 (1st Cir. 1972); *Dupre v. G.D. Searle & Co.*, 1987 U.S. Dist. LEXIS 16769 (D.N.H. Apr. 28, 1987).

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 10

Plaintiff's Failure to Follow Instructions

If you determine that a defect existed in Mutual's sulindac and that defect caused it to be unreasonably dangerous, and that Mutual is liable, you should then go on to determine if Ms. Bartlett committed misconduct that contributed to cause her injuries. With respect to her alleged misconduct, Mutual bears the burden to prove that it is more likely than not that she committed misconduct in the use of sulindac.

Misconduct includes, but is not necessarily limited to, abnormal use of the product, use of the product contrary to instructions, misuse of the product, failing to discover or foresee dangers which the ordinary person would have discovered or foreseen, and voluntarily and unreasonably proceeding to encounter a known danger.

If you find that the misconduct of Ms. Bartlett, if any, was not reasonably foreseeable by Mutual, Ms. Bartlett is not entitled to recover for her injuries.

Even in a case in which plaintiff's misconduct was reasonably foreseeable by the defendant, the plaintiff is not entitled to recover if that misconduct was more than 50 percent responsible for his/her own injuries. If such plaintiff's misconduct contributed 50 percent or less to cause his/her own injuries, you may still return a verdict in favor of the plaintiff, but the amount of the verdict will be reduced by the court by the percentage represented by the plaintiff's misconduct.

(*See* New Hampshire Civil Jury Instruction 23.6, in part; RSA 507:7-d)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 11

"State of the Art" Defense

A manufacturer may defend against a claim of design defect by demonstrating that it has complied with the state of the art. The state-of-the-art test requires that the design be viewed in light of what was scientifically (and) technologically (and economically) feasible when the product was distributed/sold. The test is not what the industry was doing when the product was distributed/sold. The test is what the industry could feasibly have been doing scientifically (and) technologically (and economically) when the product was distributed/sold.

New Hampshire Civil Jury Instruction 23.7, in part

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 12

Superseding Cause

Mutual may avoid liability if it demonstrates that the conduct of someone other than Ms. Bartlett or Mutual caused plaintiff's injuries. Remember that Ms. Bartlett must prove that the cause of her injuries was a defect in the product. If she has shown that a defect in the product was at least one of the causes of her injuries, the burden of proof is then on Mutual to prove that another person's conduct was actually the sole cause of the plaintiff's injuries. Mutual must show that the other person's actions could not be reasonably foreseen by it. If you find that Mutual could reasonably foresee the other person's conduct, then you should not consider the other person's conduct in reaching your verdict. Under our law, unless someone other than Mutual was the sole cause of the plaintiff's injuries, you may find Mutual liable for Ms. Bartlett's injuries even though Mutual was only partly at fault. If someone other than Mutual was a cause, but not the sole cause, of plaintiff's injuries, then you will apportion fault among the parties.

New Hampshire Civil Jury Instruction 23.8

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 13

Apportionment

If the greater weight of the evidence does not support Mutual's defenses, and the greater weight of the evidence does support one or more of the claims of Ms. Bartlett, then you should determine and write on the verdict form what percentage of the total responsibility is chargeable to Mutual.

If, however, the greater weight of the evidence shows that generic sulindac was defective and unreasonably dangerous when sold by Mutual and the evidence also shows that Karen Bartlett or Dr. Ergin were negligent, and the negligence of either contributed as a legal cause of injury sustained by Ms. Bartlett, you should determine and write on the verdict form what percentage of the total negligence of all parties is chargeable to each.

In both instances, you also should write on the verdict form what percentage of the total negligence or other fault is chargeable to Ms. Bartlett, and/or to Dr. Ergin.

(*See DiBenedetto v. CLD Consulting Engineers, Inc.*, 153 N.H. 493 (2006); *Bohan v. Ritzo*, 141 N.H. 210 (1996; RSA 507:7.)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 14

Duty of Reasonable Care – No Duty to Anticipate Negligence

The duty to use reasonable care arises from the risk to others which could be reasonably foreseen. Thus, a person may not be found negligent if he or she could not reasonably foresee that its conduct would result in an injury to another, or its conduct was reasonable in light of the risks. Also bear in mind that a person has no duty to anticipate the careless conduct of another.

New Hampshire Civil Jury Instruction 6.16 and 6.3

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 15

Industry Standards

You have heard testimony that Mutual complied with certain industry standards with regard to generic sulindac. You may consider those standards and whether Mutual complied with them along with other evidence presented in determining whether Mutual used reasonable care with regard to generic sulindac.

(*See Thibault v. Sears, Roebuck & Co.*, 118 N.H. 802, 814 (1978))

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 16

Legal Cause – Defined

A defect in a product is a legal cause of injury if it directly and in natural and continuous sequence produces or contributes substantially to producing such injury so that it reasonably can be said that, but for the defect, the injury would not have occurred.

(*See LeFavor v. Ford*, 135 N.H. 311, 313 (1992); *Rawson v. Bradshaw*,125 N.H. 94, 101 (1984); *Trull v. Volkswagen of America, Inc.*, 145 N.H. 259, 266-67 (2000).)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 17

Legal Cause

In order to be regarded as a legal cause of injury, a defect in a product need not be the only cause. A defect may be a legal cause of the injury even though it operates in combination with the act of another or some other cause if such other cause occurs at the same time as the defect has its effect, and if the defect contributes substantially to producing such injury.

(*See* N.H. Civil Jury Instructions § 7.1, 6.1; *LeFavor v. Ford*, 135 N.H. 311, 313 (1992).)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 18

Comparative Fault

This case has been tried under the law of comparative fault. Under this law, you may find that the plaintiff's injuries were the result of the legal fault of the defendant, the legal fault of the plaintiff, the legal fault of Dr. Ergin, or to some degree, the legal fault of each of them. If the greater weight of the evidence does not support Ms. Bartlett's design defect claim against Mutual, your verdict must be for Mutual. However, if the greater weight of the evidence does support Ms. Bartlett's design defect claim against Mutual, then you shall consider the defenses raised by Mutual.

With regard to comparative negligence, the issues for your determination are whether Karen Bartlett was negligent and, if so, whether her negligence was a contributing legal cause of her injuries. You also must determine whether Ms. Bartlett or Dr. Ergin were negligent or otherwise at fault for Ms. Bartlett's injuries, and if so, whether that negligence or fault was a contributing legal cause of Ms. Bartlett's injuries.

Under this law, a plaintiff who is more than 50% legally at fault for the incident cannot recover damages arising out of the incident. If a plaintiff is 50% or less legally at fault, she can recover damages -- but only in proportion to the amount of the defendant's legal harm.

For example, suppose plaintiff was found to be 51% legally at fault for an incident. In that case, the plaintiff would recover nothing. On the other hand, suppose a plaintiff and a defendant were each found

50% legally at fault and the total of the plaintiff's damages were found to be $1.00. In that case, the plaintiff would recover 50 cents. Thus, even if you find that the plaintiff and the defendant are equally at fault, the plaintiff is still entitled to recover damages which you find were caused by the accident; such damages will, however, be reduced by half. Understand that you must determine the full amount of any damages suffered by the plaintiff; it will then be my responsibility to reduce those damages by any percentage of fault which you find attributable to the plaintiff.

As I have explained, in order for the plaintiff to recover, she must prove that the defendant is legally at fault for the accident and injuries. However, in connection with the defendant's claim that the plaintiff is at fault, the defendant carries the burden of proof. This is, the defendant must prove, by a preponderance of the evidence, that the plaintiff was legally at fault. In deciding whether the defendant has met its burden of proof, you must apply the law which I have given you regarding legal fault. Thus, the defendant must prove that the plaintiff failed to exercise care and that such failure was a substantial factor in bringing about his/her injury.

At the conclusion of my instructions, I will provide you with a special verdict form which asks you several questions. These questions will help you properly analyze the comparative fault issues, and I will explain the form in detail then.

New Hampshire Civil Jury Instruction 8.1

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 19

Elements of Personal Injury Damages

If your verdict is for Mutual, you will not consider the matter of damages. But if your verdict is for Ms. Bartlett, you should determine and write on the verdict form, in dollars, the total amount of damage which the greater weight of the evidence shows Ms. Bartlett sustained as a result of her injury, including any such damages that she is reasonably certain to incur or experience in the future.

In determining the total amount of any damages sustained by Ms. Bartlett, you shall consider only the following elements:

1. The reasonable value of medical (hospital, nursing) care, services, and supplies reasonably required and actually given in the treatment of plaintiff (and the reasonable value of similar items that will probably be required and given in the future).

2. The present value of lost wages to date or wages plaintiff probably would have earned to date if he/she had not been injured.

3. The present value of plaintiff's loss of earning capacity, that is, any future wages that plaintiff probably would have earned if he/she had not been injured.

4. Reasonable compensation for pain and suffering experienced to date and which will probably be experienced in the future. This includes compensation for physical pain, discomfort, fears, anxiety, mental and emotional distress, and loss of enjoyment of life--that is, the inability to carry on and enjoy life in a manner had the accident not occurred.

No definite standard (or method of mathematical calculation) is prescribed by law by which to fix reasonable compensation for pain and suffering. Nor is the opinion of any witness required as to the amount of such reasonable compensation. In making an award for pain and suffering you should exercise your reasonable judgment and the damages you determine have to be full, fair and adequate in light of the evidence.

New Hampshire Civil Jury Instruction 9.6

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 20

No Punitive Damages

The purpose of an award of damages is to compensate the plaintiff for her injuries, not to punish the defendant. You are not permitted to award money damages for the purpose of punishing the defendant or of making an example of it for the public good or of preventing it and others from similar conduct, or to compensate the plaintiff beyond the instruction I have given you regarding compensatory damages.[9]

(*See* R.S.A. 507:16; *Fay v. Parker*, 53 N.H.342, 384, 1872 WL 4394 at *43 (1872) (going to great lengths to explain that so-called "enhanced" or "liberal" compensatory damages were merely an unfortunate linguistic relic of courts grappling with the notion of damages for mental suffering). Defendant maintains

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[9] Mutual maintains that "enhanced compensatory damages" are not legally tenable, but in the event that the Court holds otherwise, the following additional paragraph from the N.H. Civil Jury Instructions should be used:

> If you find that plaintiff suffered actual damages that were caused or substantially caused by the conduct of the defendant, there are certain circumstances under which the law permits you, but does not require you, to consider an award of additional damages to reflect aggravating circumstances. These damages are called "enhanced damages" or "liberal compensatory damages." You may award these damages only if you find that the defendant's conduct was more probably than not wanton, malicious, or oppressive. "Wanton" means reckless indifference or disregard of consequences. "Malicious" means ill-will, hatred, hostility, or bad motive. "Oppressive" means abuse of power.

that the decisions which have followed have failed to grasp the import of *Fay v. Parker*. *E.g.*, *Munson v. Raudonis*, 118 N.H. 474, 479 (1978).)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 21

Duty to Mitigate

A person who has been injured by the wrongful act of another is obligated to exercise reasonable care and effort to avoid loss and to minimize the damages. She may not recover for losses which could have been prevented by her making reasonable efforts without undue risk on her part. She may also recover expenditures reasonably incurred to avoid or minimize

It is the duty of a person who has been injured to use reasonable effort without undue risk or expense in caring for her injuries and reasonable means to prevent their aggravation and to accomplish healing.

When a person does not use reasonable efforts to care for her own injuries, and those injuries are aggravated as a result of such failure, the responsibility of another whose act or omission was a cause of the original injury, is limited to the amount of damage that would have been suffered had the injured person herself exercised the effort required of her.

The fact that a competent physician advised an injured person to submit to a course of treatment or operation does not justify an inference that the injured person was unreasonable in declining such treatment or operation. Other factors as confronted the injured person must be considered in determining whether, although she refused or failed to follow the physician's advice, she nevertheless exercised reasonable efforts in caring for herself and her injuries.

You should not include in the verdict such damages, if any, that the plaintiff could have avoided by reasonable effort, without undue risk or expense.

New Hampshire Civil Jury Instruction 9.15

GIVEN:_____

REFUSED:_____

MODIFIED:_____

DEFENDANT'S REQUESTED JURY INSTRUCTION NO. 22

Standard Final Instruction

Members of the jury:

The principles of law given to you in these instructions, as I said before, are intended to guide you in reaching a fair and just verdict in this case which is of utmost importance to the parties as well as the court. You should decide the facts of this case without passion, without sympathy, and without prejudice but with honesty and understanding. You should be conscientious of a just result in this case as that is your highest duty as officers of this court. You will render your verdict by filling out the jury verdict form provided.

Your verdict must be unanimous, that is, you must all agree. In order to ensure that the verdict is in fact unanimous, the verdict of the jury as a whole must be the verdict of each of you individually.

The duty of the foreperson of the jury is to act very much like the chairperson of a committee, making certain that each and every member of the jury is given a full and fair opportunity to present his or her views and opinions on each of the issues presented to you for determination. You are each instructed to consider each other's views and opinions and in the final instance reach your own conclusions.

In the event you have some question relative to my instructions or the legal issues presented in this case, please put the question in writing, have the foreperson sign the question and, if you remember to do so, write down the time you presented the question to the court officer. He will then present the question to me for

response which I will furnish you after I have had the opportunity to discuss the question and proposed answer with counsel. I cannot comment on the evidence, as that is not my role. As I said previously, it is up to you to evaluate the evidence and you must use your own recollection of it.

You may now retire and commence your deliberations, and I will see to it that the exhibits that have been entered in this case are delivered to you.

New Hampshire Civil Jury Instruction 1.9

GIVEN: _____

REFUSED: _____

MODIFIED: _____

DEFENDANT'S PROPOSED VERDICT FORM

We, the jury, return the following verdict:

1. Did you find by the greater weight of the evidence each of the following items?

- Ms. Bartlett took a generic pharmaceutical product manufactured by Mutual containing the active ingredient sulindac and normal binders and fillers; and
- The generic pharmaceutical product Ms. Bartlett took had a defect because the product contained an additional ingredient, other than sulindac and the normal binders and fillers in the product, that the ordinary consumer would not have expected to be in the product; and
- The additional ingredient, and not the sulindac or normal binders and fillers in the product, made the product defective; and
- The defective condition of Mutual's pharmaceutical product rendered it unreasonably dangerous; and
- The use of the product was reasonably foreseeable by Mutual; and
- Mutual's pharmaceutical product was not unavoidably unsafe; and
- Dr. Ergin was unaware of the dangers and risks associated with Mutual's pharmaceutical product; and
- The defective condition of Mutual's pharmaceutical product was a legal cause of the injury to Ms. Bartlett.

YES _____ NO _____

If your answer to question 1 is YES, answer question 2. If your answer to question 1 is NO, sign the verdict form and return it to the courtroom.

2. Do you find by the greater weight of the evidence that Dr. Ergin was negligent and that his negligence was a legal cause of Ms. Bartlett's injuries?

YES _____ NO _____

Proceed to question 3.

3. Do you find by the greater weight of the evidence that Ms. Bartlett was negligent and that her negligence was a legal cause of her injuries?

YES _____ NO _____

If your answer to questions 2 and 3 were both "NO," please skip question 4 and proceed directly to question 5. If your answer to either question 2 or question 3 or both was "YES," please answer question 4.

4. State the percentage of any negligence or fault, which was a legal cause of loss, injury, or damage to Karen Bartlett that you charge to:

Mutual _____%

Dr. Ergin _____%

Ms. Bartlett _____%

Total must be 100%

5. By answering the following questions you will determine the damages if any that Karen Bartlett sustained as a result of the incident in question. In determining the amount of damages, do not make any reduction because of the negligence, if any, of Dr. Ergin or Ms. Bartlett. If you find that Dr. Ergin or Ms. Bartlett was to any extent negligent, the court in entering judgment will make an appropriate reduction in the damages awarded.

a. What is the amount of any medical or other expenses, including attendant care and treatment, resulting from Ms. Bartlett's injury?

$_____

b. What is the amount of any medical expenses paid by Ms. Bartlett?

$_____

c. What is the amount of any loss by Ms. Bartlett in pain and suffering as a result of the injury.

$_____

d. What is the amount of any loss by Ms. Bartlett in lost wages, including future earnings as a result of the injury.

$_____

6. You also must determine whether the evidence shows that Mutual acted maliciously, oppressively or wantonly. If you so find, indicate the amount of enhanced compensatory damages as a result of the injury.

$_____

New Hampshire Civil Jury Instruction 8.2 Special Verdict Form (as modified)

GIVEN: _____

REFUSED: _____

MODIFIED: _____

Respectfully submitted,

/s/ Paul J. Cosgrove
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CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of July, 2010, a true and correct copy of the foregoing document was electronically filed with the Clerk of Court using the ECF system, and notice of the filing was given via electronic notice to the following:

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/s/ Paul J. Cosgrove

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

KAREN L. BARTLETT,

vs.

MUTUAL PHARMACEUTICAL COMPANY, INC.

CASE NO.: 08-cv-358-JL

Judge Joseph N. Laplante

PLAINTIFF'S VOIR DIRE REQUESTS

Comes now Plaintiff Karen Bartlett, and simultaneously with her Pre-Trial Statement files this, her Voir Dire Requests, stating as follows:

I. INTRODUCTION

As allowed by Rule 47 of the Federal Rules of Civil Procedure, and in accordance with Local Rule 16.2, Plaintiff respectfully requests that the Court distribute the attached Jury Questionnaire to all potential jury members prior to the day that Voir Dire occurs, and allow both parties the ability to use up to 3 hours each to conduct attorney lead Voir Dire.

II. ARGUMENTS AND AUTHORITIES

The primary purpose of the *voir dire* of jurors is to make possible the empaneling of an impartial jury through questions that permit the intelligent exercise of challenges by counsel." *See United States v. Blount*, 479 F.2d 650, 651 (6th Cir. 1973). Federal law specifically incorporates the common law right to strike a juror in a civil matter for cause to be determined by the trial court and also incorporates the common law right to peremptorily challenge a prospective juror for suspicion of bias or partiality. *See* 28 U.S.C. § 1870. Under Section 1870, a trial court

acts properly by striking "for cause" a venire panel members who had been previously sued in a personal injury case and previously served on a jury in a personal injury case a as both experiences can create bias. *See Vanskike v. ACF Industries, Inc.*, 665 F2d 188, 207 (8th Cir. 1981), *cert den.* 455 US 1000, 71 L Ed 2d 867, 102 S Ct 1632 (1982).

In *Fiezter v. Ford Motor Company*, the Seventh Circuit cited a long line of criminal trial cases and held that even in a civil case that the trial court has the affirmative duty to pose questions that go beyond what may bring out information that would disqualify the juror for cause and that "it is essential to explore the backgrounds and attitudes of the jurors to some extent in order to discover actual bias, or cause[,]" and that the examination must reveal inquiry adequate "to call to the attention of the veniremen those important matters that might lead them to recognize or to display their disqualifying attributes." *See Fiezter v. Ford Motor Company* 622 F.2d 281, 284-85 (7th Cir. 1980)(citations omitted).

Accordingly, numerous courts of appeals have agreed that "it is an abuse of discretion for the district court to refuse to probe the jury adequately for bias or prejudice about material matters on request of counsel." *See, Pitasi v. Stratton Corp.*, 968 F.2d 1558, 1563 (2d cir. 1992) *citing, inter alia, Darbin v. Nourse*, 664 F.2d 1109, 1113-14 (9th Cir. 1981); *see also, Art Press, Ltd. v. Western Printing Machinery Co.*, 791 F.2d 616, 618 (7th Cir. 1986)(reversing civil verdict due to inadequate voir dire).

Further, the First Circuit Court of Appeals has made clear that when there is an identifiable potential bias, trial courts should not only asks questions to the

entire venire panel, but should ask questions to each member separately, as the "absence of response, achieves little or nothing by way of identifying, weighing, or removing any prejudice from prior publicity." *See Patriarca v. United States*, 402 F.2d 314, 317-18 (1st Cir. 1968).

A. Plaintiff Seeks to Elicit Questions Within Well Defined Parameters

Under the Federal Rules of Civil Procedure, the trial court has discretion in the manner and means of voir dire. See Fed. R. Civ. P. at Rule 47. As *Voir Dire* has been part of American jurisprudence since prior to the American Revolution, Plaintiff seeks to ask questions in the following areas, each of which has been litigated to be an area of permissible questioning under the proper circumstances in order to determine the potential for bias to either seek a preemptory or for cause strike:

- Preconceived notions of facts at Issue, similar business as parties, or similar accident as the one in controversy – *Fietzer v. Ford Motor Co.*, 622 F.2d at 284-85.
- Involvement in similar business as the parties, *See id.*
- Involvement in prior similar accidents or injuries; *See id.; see also Vanskike,* 665 F2d at 207; *see also Photostat Corp. v. Ball*, 338 F.2d 783 (10th Cir. 1964)(Reversible error and new trial granted in civil trial when trial court refused to allow questions on prior similar injuries); *see also, U.S. v. Poole*, 450 F.2d 1082 (3rd Cir. 1972)(Error to not allow

questions as to victim of similar circumstances);

- Hesitancy to award a large verdict. *See Cleveland v. Cleveland Elec. Light Illum. Co.*, 538 F.Supp 1240 ()(Court allowed inquiry into "hesitancy" into multimillion dollar verdict); *see also Geehan v. Monahan*, 382 F.2d 111, 115 (7th Cir. 1967)(Court allowed inquiry into whether members would have "hesitancy" to award specific dollar amount of if satisfied the evidence showed those damages);
- Panel Members current and prior employment as it relates to:
  - Law, lawyers, legal profession, the justice system – *See Progner v. Eagle*, 377 F.2d 461, 461-62 (4th Cir. 1967)(Error not to allow questions related to outside legal knowledge or employment);
  - Governmental employment – *See Murford v. U.S.*, 339 U.S. 258, 259 (1950)(Reversible error held for denying questions related to government employment)
  - Employment connection to or relationships with law enforcement – *See U.S. v. Lewin*, 467 F.2d 1132, 1138 (7th Cir. 1972)(reversible error to not allow questions related to law enforcement connections);
- Views on the legal theories or principles involved in the case – *See U.S. v. Blount*, 479 F.2d 650, 651-52 (6th Cir. 1973)(reversible

error to not ask requested question on burden or proof);

- Educational background– *See United States v. Alessandrello*, 637 F.2d 131, 134(D. NJ 1980) (Trial Court asked about education);
- Panel members' knowledge of pre-trial publicity as a possible area of bias – *See U.S. v. Lewin*, 467 F.2d 1132, 1138 (7th Cir. 1972)(reversible error when insufficient questions of knowledge of publicity);
- Attitudes or membership in political groups – *See U.S. v. Dellinger*, 472 F.2d 340, 368-69 (7th Cir. 1972); and,
- Prior Jury Service – *See Vanskike*, 665 F2d at 207 (trial court properly stuck for cause based on prior similar jury service); *see also U.S. v. Poole*, 559 F.2d 955, 958 (5th Cir. 1977)(Reversible error because *Voir Dire* is "meaningless" without the ability to ask jurors about serving on prior similar juries).

Accordingly, Plaintiff seeks the ability to ask questions on each of the above areas, and as allowed under Rule 47, to do so directly.

B. The Social Science of Jury Questioning has Long Demonstrated that Open-Ended Questions from Counsel is More Effective Than Questions from the Court

If the purpose of Voir Dire is to allow the parties to have sufficient information to achieve justice by making fully informed use of their Plaintiff strikes for cause and preemptory strikes, then the most appropriate use of Voir Dire questioning should be the method that is most likely to reveal juror bias. Thanks

to the use of social sciences, it has been known for decades that Juror's are more likely to answer questions regarding potential bias when being questioned by the parties' counsel then when being questioned by the Court. See, e.g., "Juror Self-Disclosure in Voir Dire: A Social Science Analysis," 56 Ind. L.J. 245 (1981)

Indeed, her 1987 article in the Journal of Law and Human Behavior, a detailed analysis conducted under a grant by the National Institute for Justice at the Department of Justice on the role of the trial judge in Voir Dire reached the following results:

1. The influence of a judge is so pervasive that venire members are twice as likely to change their response on cross questioning by a judge than by an attorney; (p. 131)
2. Noted scholars are in agreement in disputing the assertion that judge led voir dire produces stronger; (p. 132)
3. Social scientists have long noted a societal inability to open up to persons who have the ability to punish us for our honesty; (p. 133)
4. Attorneys, even when not using proper techniques to put venire members at ease, still were more readily able to elicit truthful disclosures than judges (p. 144);
5. The Judge's role as an authority figure is a positional impediment to venire member candor; (P 144);
6. Even 3 ministers were convinced to change their answers by the judge in the experiment;

7. The data demonstrates that it is hard for venire members to have candor, and harder for them to have candor with the authority figure judge than with the attorneys.

See, Jones, Susan, E., "Judge Versus Attorney Conducted Voir Dire," J. Law and Human Behavior, Vol. 11, No. 2 (Plenum Pub. 1987).

Accordingly, Plaintiff's respectfully asserts that the most appropriate manner to proceed in voir dire in order to best allow the parties to fully determine the actual bias of potential jury members is with attorney lead questioning, as is expressly allowed under Rule 47.

C. The Use of Jury Questionnaires is Proper and Frequently Used

Additionally, in attempting to allow the parties to obtain appropriate information on members of the Venire Panel, federal courts have routinely been using the use of jury questionnaires sent to panel members prior to the day of Voir Dire, so that the parties may use their Voir Dire time in a more efficient manner. *See, e.g., United States v. Quinones,* 511 F.3d 289, 300 (2nd Cir. 2007)("The use of a jury questionnaire as tool to preliminary screen venire members falls well within the district court's discretion in conducting voir dire") *See, also, Edwards v. Hyundai Motor Mfg. Ala.*, LLC, 2010 U.S. Dist. LEXIS 31355 (Court sent Questionnaire to civil venire members prior to trial – new trial granted when biased jury provided false answer). Indeed, attached as Exhibits B – E are four such federal jury questionnaires, used recently by federal trial courts to assist the parties in picking a jury free of bias.

Additionally, Plaintiff is also attaching its proposed pre-trial jury Questionnaire. *See* Exhibit "F." Unlike some of the large and unwieldy documents attached as Exhibits D-E, Plaintiff's proposed jury questionnaire is comparatively short. Additionally, the Court can also review the Plaintiff's proposed Questionnaire and see that Plaintiff is seeking the categories of information that the above cases detailed in Section II.A. demonstrate are appropriate questions to assist the Plaintiff (and the Defendant) in picking an unbiased jury.

CONCLUSION

The scope of potential questions to venire members to identify and remove potentially biased jurors is broad. In order to achieve justice, both parties have a right to a jury free of bias – and as the Fifth Circuit has stated, "Voir Dire is meaningless" without the ability to ask meaningful questions.

The social science experts for decades have identified that venire members are less likely to reveal actual bias if they are questioned directly by the judge – a figure of respect and authority that typical venire members seek to please by providing the "correct" answer. Accordingly, Plaintiff's request that each side have sufficient time to directly ask questions to the venire members, and if specific instances of potential bias are identified, then have individual voir dire of specific venire members without the entire venire panel present.

Finally, to allow this process to proceed as speedily as possible – in conformity with both parties needs to identify potential biases – the Plaintiff seeks the use of the attached pre-trial Jury Questionnaire or a similar document.

The Plaintiff respectfully requests that each party be allowed up to 3 hours for voir dire and that this should be sufficient for both parties to make educated use of their strikes for cause and preemptory strikes. Obviously, depending on the makeup of the panel, it is possible that one of both of the parties might not need this amount of time. However, for a trial of this magnitude and importance, the parties should be allowed a voir dire that allows the Court and all parties to be certain that no biases exist and that a fair trial can be obtained.

WHEREFORE, Plaintiff respectfully requests:

1) That the Court allow each party to directly asks questions to members of the Venire Panel;
2) That the Court allow each party to take up to 3 hours for their Voir Dire questions;
3) That the Court allow each party to point out individual Venire Panel Members who should be asked questions separately to follow up on potential issues of bias, prejudice, or inability to follow the law in rendering a verdict;
4) That allow the Plaintiffs to have the attached Jury Questionnaire filled out by all prospective Members of the Venire Panel prior to their coming to the Court so that the Parties may have time to evaluate answers prior to the empaneling of the Venire Panel for the purposes of assisting the speedy and proper purposes of voir dire.

Dated the 6th day of July, 2010.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that this document was filed by the ECF system and served on all counsel of record electronically as a result thereof on the 6th day of July, 2010.

/s/ Eric N. Roberson
Eric N. Roberson

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Mutual Pharmaceutical Company, Inc.

Civil No. 08-cv-358-J
Opinion No. 2010 DNH 123

MEMORANDUM ORDER

This products liability case presents numerous disputes over the admissibility of expert testimony. Plaintiff Karen Bartlett, who took the generic drug Sulindac and suffered severe side effects, brought suit against the drug's manufacturer, Mutual Pharmaceutical Company, asserting state-law claims of strict products liability and negligence based on defective design. She alleges, in particular, that Sulindac's safety risks outweigh its medical benefits, making it an unreasonably dangerous product. This court has subject-matter jurisdiction under 28 U.S.C. § 1332(a)(1) (diversity), because Bartlett is a New Hampshire citizen and Mutual is located in Pennsylvania.

Earlier in the case, this court denied Mutual's motion for judgment on the pleadings, *see* Fed. R. Civ. P. 12(c), rejecting the argument that Bartlett's claims were pre-empted by federal law. *Bartlett v. Mut. Pharm. Co.*, 659 F. Supp. 2d 279 (D.N.H. 2009). After discovery, both parties moved for summary judgment. *See* Fed. R. Civ. P 56. This court recently granted each of their motions in part, eliminating several claims and defenses, but allowing Bartlett to proceed

to trial on her defective design claims. *Bartlett v. Mut. Pharm. Co.*, 2010 DNH 112.

Both parties have now moved to exclude or limit the testimony of each other's expert witnesses at the upcoming trial. *See* Fed. R. Evid. 702. After reviewing their submissions, this court grants the motions in part and denies them in part. The parties' experts have sufficient qualifications and a sufficient foundation to support most of their proffered opinions. But they may not offer legal opinions that impinge upon the roles of the judge a· d jury, nor may they speculate about what the Food & Drug Administration ("FDA") would have done in hypothetical circumstances.

I. Applicable legal standard

"The touchstone for the admission of expert testimony in federal court litigation is Federal Rule of Evidence 702." *Crowe v. Marchand*, 506 F.3d 13, 17 (1st Cir. 2007). Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. As the structure of this rule suggests, before the jury can consider expert testimony over the adverse party's objection, the trial judge,

serving as "gatekeeper," must determine whether the testimony has a proper foundation. *See, e.g., Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). The party introducing the testimony bears the burden of proving its admissibility. *Id.* at 592. "Rule 702 has been interpreted liberally in favor of the admission of expert testimony." *Levin v. Dalva Bros., Inc.*, 459 F.3d 68, 78 (1st Cir. 2006).

While presented as Rule 702 challenges, many of the parties' requests would be more accurately described as motions in limine, since they seek to exclude testimony for lack of relevance rather than lack of foundation. Like all evidence, expert testimony must be relevant to the issues in the case. *See, e.g., United States v. Pena*, 586 F.3d 105, 110 (1st Cir. 2009). Evidence is relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. The relevance standard is also interpreted liberally. *See, e.g., Mitchell v. United States*, 141 F.3d 8, 14 (1st Cir. 1998).

II. Background

The factual and procedural background of this case is set forth in the recent summary judgment ruling, *Bartlett*, 2010 DNH 112, at 3-8, and need not be repeated here.

III. Analysis

A. Bartlett's motion

Bartlett has made 37 requests to exclude or limit testimony by Mutual's experts. Some of her requests will be analyzed together, since they involve closely related issues.

i. Generic drug labeling (Requests 1-8, 22, 29-30)

The first issue raised by Bartlett's motion is whether Mutual's experts may testify about federal law, FDA policy and procedure, or industry practice with regard to generic drug labeling.[1] This court has already ruled that federal law allows generic drug manufacturers to strengthen a generic drug's safety warning unilaterally. *See Bartlett*, 659 F. Supp. 2d at 302. But Mutual's experts intend to testify that such changes would be inconsistent with the "real-life" FDA policy and industry practice, which is for only the manufacturer of the brand-name or "reference listed" drug to make such changes. Bartlett argues that this testimony must be excluded from trial because it would be contrary to this court's legal ruling and thus confusing to the jury.

Since "it is the judge's role, not a witness's, to instruct the jury on the law," this court "has broad discretion to exclude expert opinion evidence about the law that would impinge on the roles of the judge and the jury" or would cause "jury confusion." *Pelletier v. Main St. Textiles, LP*, 470 F.3d 48, 54-55 (1st Cir. 2006). Indeed, "[e]xpert testimony proffered solely to establish the meaning of a law is presumptively

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[1] Although this court recently granted summary judgment to Mutual on Bartlett's failure-to-warn claims, Sulindac's label is still relevant to this case in at least one respect, which is that Mutual's "comment k" defense depends on the adequacy of the product's warning, among other things. See Bartlett, 2010 DNH 122, at 26 (discussing Restatement (Second) of Torts § 402A, cmt. k (1965)). This court will therefore resolve all of the expert challenges relating to Sulindac's label, without prejudice to any trial objections challenging the relevance of such evidence in light of this court's summary judgment ruling.

improper." *United States v. Mikutowicz*, 365 F.3d 65, 73 (1st Cir. 2004); *see also Nieves- Villanueva v. Soto-Rivera*, 133 F.3d 92, 99 (1st Cir. 1997). And even if such testimony has independent factual significance, i.e., aside from the content of the law, it still may be excluded "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury." Fed. R. Evid. 403; *see also United States v. Ahrendt*, 560 F.3d 69, 76 (1st Cir. 2009).

As an initial matter, Mutual concedes that its experts cannot and will not "provide testimony that interprets . any statutes or regulations." This concession is well taken. Again, such testimony would be presumptively improper. *See Mikutowicz*, 365 F.3d at 73. It would also be unfairly prejudicial to Bartlett and confusing to the jury, because it would conflict with this court's legal rulings and, presumably, its jury instructions. Since Mutual has not opposed that part of Bartlett's request, it is granted. No defense experts may testify about the meaning or applicability of the law. *See* Fed. R. Evid. 403; Pelletier, 470 F.3d at 54-55 (affirming exclusion of expert testimony regarding applicability of federal workplace safety regulations).

Mutual argues that, so long as its experts steer clear of the actual statutes and regulations, they should be allowed to testify about FDA policy and procedure. But such testimony raises many of the same concerns, because it is based largely on FDA documents that analyze or parrot the language of the relevant statutes and regulations. Indeed, they are some of the very same documents that this court interpreted in its earlier ruling. *See, e.g., Bartlett*, 659 F. Supp. 2d at 293 n.19 (rejecting Mutual's

interpretation of 2004 industry guidance); *id.* at 294 n.21 (rejecting Mutual's interpretation of "the FDA's remarks in proposing and promulgating these regulations"). The testimony is thus a roundabout way of challenging this court's ruling. As such, it creates the same danger of undue prejudice and confusion as testimony about the statutes and regulations themselves. *See* Fed. R. Evid. 403.

Moreover, Mutual's experts have not pointed to any evidence of the supposed policy in action, so their testimony about it amounts to little more than "speculation as to what FDA might have done in hypothetical circumstances." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 550 (S.D.N.Y. 2004) (excluding such speculation). Both parties seem to agree that there is no historical evidence, at least in this record, that the FDA has either accepted or rejected previous attempts by generic drug manufacturers to unilaterally strengthen a drug warning. So the policy is not based on what the FDA has actually done; rather, it is based on what the FDA purportedly believed or would have done, according to former FDA officials. Such testimony is not sufficiently reliable to satisfy Rule 702(2).

If Mutual had "simply no other practical means to prove the point," then this court might be more inclined to admit the testimony about FDA policy and procedure, despite its problems. *United States v. Fields*, 871 F.2d 188, 198 (1st Cir. 1989); *see also United States v. Scott*, 270 F.3d 30, 51 (1st Cir. 2001) (noting that the "availability of other means of proof" is an "appropriate factor" to consider in determining whether evidence should be excluded). But that is not the case. Mutual can make its point effectively

through testimony about industry practice, without needing to try to cast it as a matter of FDA policy and procedure. Specifically, Mutual's experts can testify that the longstanding industry practice is for the manufacturer of the brand-name or "referenced listed" drug to make changes to the drug's label, and for generic manufacturers simply to parrot any such changes.

Bartlett argues that testimony about industry practice is also unduly prejudicial and confusing to the jury. But this court disagrees. "[I]n general, the customs and practices of an industry are proper subjects for expert testimony." *Pelletier*, 470 F.3d at 55. The jury is fully capable of understanding that there may be a gap between what the law requires and what industry members actually do. Indeed, conformity with industry practice is not an absolute defense to liability under New Hampshire law, because "entire industries may lag behind" the standard of care. *Heath v. Sears, Roebuck & Co.*, 123 N.H. 512, 530 (1983). But it is nonetheless a factor that the jury may consider in evaluating strict liability claims, *see, e.g.*, *Thibault v. Sears, Roebuck & Co.*, 118 N.H. 802, 814 (1978), and negligence claims, *see, e.g.*, 8 Richard B. McNamara, *New Hampshire Practice* § 4.74, at 4-107 (3d ed. 2003).

In sum, this court concludes that Mutual's experts may not testify about federal law (whether directly or under the guise of FDA policy and procedure) on the issue of whether a generic manufacturer has the ability or responsibility to strengthen a generic drug's safety warning. The probative value of such testimony is substantially outweighed by the danger of unfair prejudice and jury confusion. *See* Fed. R. Evid. 403.

Witnesses may, however, testify about industry practice in that regard.

ii. Late production of prior transcript (Request 9)

The next issue is whether Dr. Stewart Ehrreich, designated by Mutual as a pharmacological expert, should be precluded from testifying altogether because Mutual failed to produce (until the day of his deposition) a transcript from a deposition he gave in another case, where he testified that the label for ibuprofen was inadequate because it did not mention the possibility of death. According to Bartlett, the parties had agreed that any such transcripts would be produced at least seven days before Dr. Ehrreich's deposition. Mutual, however, denies that any such agreement existed (or that Bartlett complied with it for her own experts, *see* Part III.B.i, *infra*). According to Mutual, Dr. Ehrreich "simply forgot" about that prior deposition, and Bartlett suffered no prejudice because Dr. Ehrreich testified about it anyway.

Whether an agreement actually existed between the parties is unclear from the record. Mutual proposed a schedule in which transcripts of Dr. Ehrreich's prior depositions would be produced seven days in advance of his deposition in this case, but the record contains no written acceptance of this proposal by Bartlett, and Mutual denies reaching agreement. In any event, even if an agreement existed, Bartlett has not suffered any prejudice from the late production. At his deposition in this case, Dr. Ehrreich testified in detail about the earlier case and the specific opinions that he gave there. Bartlett's counsel thus had an adequate opportunity to explore that issue. Under the circumstances, it would be inappropriate to exclude Dr.

Ehrreich from testifying. *See* Fed. R. Civ. P. 37(c)(1) (providing for exclusion of expert witness due to untimely disclosures "unless the failure was substantially justified or harmless").

iii. References to "bad luck" (Request 10)

Bartlett argues that no defense expert should be allowed to characterize her injuries as "bad luck," "luck of the draw," or any similar description, which in her view is an "advanced" expert opinion that lacks a proper foundation. It is true that the word "luck" could have a more advanced connotation in this context, with more specific implications (i.e., that Bartlett's injuries were entirely random side effects of Sulindac, unrelated to her physical traits or any other nonrandom factors). But Mutual's experts seem to be using it in a less advanced way, as a shorthand for saying that only a very small percentage of the people who have taken Sulindac have suffered SJS/TEN as a side effect. That is a probative fact for which, on the record before the court, it appears that a proper foundation has been laid under Rule 702.

Nevertheless, there is some risk that the jury, upon hearing an expert describe Bartlett's injuries as "bad luck" or "luck of the draw," might be misled into thinking that the expert intends the more advanced, implicative meaning, for which a proper foundation appears not to have been laid under Rule 702. While that risk is not very high, the probative value of the word "luck" is even lower. Mutual's experts can make the same point using other words that avoid any risk of unfair prejudice. Bartlett's request to exclude defense

experts from using the word "luck" in reference to her injuries is therefore granted.[2] See Fed. R. Evid. 403.

iv. Filling of prescription (Requests 11-13)

Next, Bartlett challenges three of Dr. Ehrreich's opinions about the filling of her Sulindac prescription: (1) that the pharmacy could have filled the prescription with another manufacturer's version of the drug; (2) that the pharmacy "likely" filled the prescription with Mutual's version because it was the cheapest; and (3) that Bartlett would have suffered the same injuries if she took one of the other versions, since they all had the same active ingredients. Bartlett argues that all of these opinions are speculative. She is right as to the second one; Dr. Ehrreich admitted in his expert report that the pharmacy's reason for choosing Mutual's version "is not known." Bartlett's request to exclude that opinion is therefore granted. *See* Fed. R. Evid. 702(1).

But the other two opinions have a sufficient foundation. Indeed, the first one is consistent with the testimony of Bartlett's doctor, who wrote the prescription. And the third one is based on the fact that the FDA requires all versions of a drug to have the same active ingredients. Bartlett notes that it is theoretically possible that her injuries were caused by Sulindac's inactive ingredients, which need not be identical. But Dr. Ehrreich made clear that his opinion

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[2] This ruling is limited to expert testimony. Depending on the context, such language may be permissible in closing argument, where counsel is generally given "some leeway to comment on the evidence." *Gomes v. Brady*, 564 F.3d 532, 538 (1st Cir. 2009); *see also Lewis v. City of Chicago Police Dep't*, 590 F.3d 427, 444 (7th Cir. 2009). Coming from an attorney rather than an expert, the word "luck" does not carry the same risk of unfair prejudice.

was based on the assumption that the active ingredients caused Bartlett's injuries, which he understood to be one of her allegations. Bartlett has not disclaimed that understanding of her claims or identified any evidence to the contrary. *See Levin*, 459 F.3d at 79 ("an expert may offer opinions based on assumptions that are not contrary to the evidence at trial"). Bartlett's request to exclude those opinions is therefore denied.[3]

v. Number of NSAID users (Request 14)

Bartlett requests that another defense expert, dermatologist Robert Stern, be precluded from testifying about the number of people in the United States who have used NSAIDs. She argues that such testimony, which Dr. Stern derived from FDA materials, is hearsay and is not relevant. But "expert opinions based on otherwise inadmissible hearsay" may be admitted if the underlying "facts or data are 'of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject.'" *Daubert*, 509 U.S. at 595 (quoting Fed. R. Evid. 703); *see also United States v. Corey*, 207 F.3d 84, 89 (1st Cir. 2000). The underlying "facts or data need not be admissible in order for the opinion or inference to be admitted." Fed. R. Evid. 703.

Experts in the field of medicine reasonably and routinely rely on FDA materials in forming their opinions on prescription drugs and their use in the United States. Thus, Dr. Stern's opinion may be admitted even if it is based on hearsay. Furthermore,

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[3] Bartlett's challenge to the relevance of such evidence will be considered in connection with her first motion in limine (document no. 185). The court expresses no opinion on that issue here.

the number of NSAID users is relevant contextual evidence for evaluating whether Sulindac is unreasonably dangerous. *See, e.g., First Marblehead Corp. v. House*, 541 F.3d 36, 42 (1st Cir. 2008) ("Testimony that provides a necessary context and framework ... can be appropriate for expert testimony."); *see also* Fed. R. Evid. 401, 402. Bartlett's request to exclude such testimony is denied.

vi. FDA awareness of SJS/TEN risks (Request 15)

Bartlett argues that Dr. Ehrreich should be precluded from testifying about the FDA's awareness of the SJS/TEN risks posed by NSAIDs because he left the agency many years ago, rendering any such opinion speculative. Actually, Dr. Ehrreich worked for the FDA from 1979 to 1986, and his opinion is that the FDA has been aware of the risks since the early 1980s, so his time at the agency overlaps with the period on which he is opining. But that is ultimately immaterial, because his testimony is based on express statements in FDA documents from the time period in question, not on mere extrapolation from his personal experience in an earlier era. On this record, his opinion appears to have a sufficient foundation under Rule 702(1). Bartlett's request to exclude the testimony is denied.

vii. Other NSAID safety warnings (Request 16)

The next issue is whether defense experts may testify about the safety warnings for NSAIDs other than Sulindac. Bartlett argues that such testimony should be allowed only if it relates to NSAIDs that were specifically evaluated by the FDA or removed from the market, because otherwise it is not relevant. Mutual argues, in response, that such testimony is relevant to whether Sulindac had an adequate

warning. This court agrees with Mutual. While conformity with industry practice is not an absolute defense to liability under New Hampshire law, it is a relevant consideration in evaluating both products liability and negligence claims. *See Thibault*, 118 N.H. at 814; 8 McNamara, *supra*, § 4.74, at 4-107; see also Fed. R. Evid. 401, 402. Bartlett's request to confine such evidence to that which favors her position is denied.

viii. Undisclosed opinions (Request 17)

Bartlett requests a blanket ruling that no defense expert may testify at trial to any opinion not already set forth in his or her expert report. It is true that an expert's report "must contain ... a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(I). And where "a party fails to provide information ... as required by Rule 26(a)," that party "is not allowed to use that information or witness to supply evidence ... at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). But whether an untimely disclosure is substantially justified or harmless cannot be determined in the abstract; it depends on the particular circumstances.[4] This court therefore declines to issue a blanket ruling, but rather will resolve any such issues as they arise at trial in the context of their specific facts.

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[4] There is also Rule 703's corollary—pertaining to the informational basis of expert opinion testimony—that such testimony may under some circumstances be based on facts "perceived by or make known to the expert *at or* before the hearing." Fed. R. Evid. 703 (emphasis added).

ix. Hypersensitivity warning (Requests 18-21)

The next issue is whether Drs. Stern and Ehrreich may testify that the hypersensitivity warning in the Sulindac label (quoted in *Bartlett*, 2010 DNH 112, at 5) served as an adequate warning of SJS/TEN. Bartlett argues that such testimony is beyond the scope of their expert reports and their expertise. Mutual appears to accept that Dr. Ehrreich cannot testify to that particular opinion, which he never properly disclosed, so Bartlett's request to exclude his testimony on this subject is granted. But Mutual argues that Dr. Stern, as one of the world's leading experts on SJS/TEN, is well qualified to testify about the meaning and adequacy of the hypersensitivity warning and that he properly disclosed his opinion in his expert report.

Contrary to what Bartlett suggests, Dr. Stern's expert report made clear that, in his opinion, the Sulindac label's hypersensitivity warning and its reference to "severe skin reactions," coupled with its cross-reference to a list of adverse reactions that included SJS/TEN, served as an adequate warning that SJS/TEN were among the risks of taking Sulindac. Indeed, one of the headings in his report is: "The warning in the 2004 sulindac labeling was clear and consistent with the knowledge concerning the risk of severe skin reactions including Stevens- Johnson Syndrome and Toxic Epidermal Necrolysis." Bartlett's argument that he failed to disclose that opinion in his report is unpersuasive.

Equally unpersuasive is Bartlett's argument that Dr. Stern lacks sufficient expertise to offer that opinion. Dr. Stern founded an international study of SJS/TEN, wrote some of the leading articles on their connection to NSAIDs (including one in the *New*

England Journal of Medicine entitled "Severe adverse cutaneous reactions to drugs"), is the chief of dermatology at Beth Israel Deaconess Hospital in Boston, is a full-time professor of dermatology at Harvard Medical School, and has chaired multiple FDA advisory committees on the safety and efficacy of drugs. *See, e.g., Forrestal v. Magendantz,* 848 F.2d 303, 308 (1st Cir. 1988) (affirming admission of doctor's expert testimony "based on his own knowledge and experience").

Bartlett argues that Dr. Stern should not be allowed to offer any opinions on Sulindac's label (including the hypersensitivity warning) because he stated at his deposition that "I'm not an expert on labeling." But Dr. Stern actually amended that statement in an errata sheet, adding the word "regs" at the end to clarify that he is not an expert on the FDA regulations applicable to drug labels. *See* Fed. R. Civ. P 30(e)(1)(B) (allowing deponent to make "changes in form or substance" to his deposition transcript). That is a plausible interpretation of what he meant. While calling the correction a "sham," Bartlett has not moved to strike it. She is, of course, free to explore it on cross-examination. *See, e.g., Daroczi v. Vt. Ctr. for the Deaf & Hard of Hearing, Inc.*, 2004 DNH 027 (Muirhead, M.J.) (citing 7 *Moore's Federal Practice* § 30.63[3] (3d. ed. 2003)).

In any event, it is Dr. Stern's qualifications, not his extemporaneous disclaimer, that determine the permissible scope of his testimony. *Cf. Pineda v. Ford Motor Co.*,.520 F.3d 237, 245 (3d Cir. 2008) (allowing expert to testify about certain aspects of product's safety warning even though he denied being a "warnings" expert, because he was an expert on the

product in question). Dr. Stern is sufficiently "qualified to render an opinion regarding the completeness or accuracy of the [Sulindac] label based on his knowledge of the risks of [Sulindac] and his own clinical experience." *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1064 (D. Minn. 2007); *see also In re Rezulin*, 309 F. Supp. 2d at 556; *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *11-12 (E.D. Pa. June 20, 2000).

Bartlett also argues that Dr. Stern's testimony about the hypersensitivity warning is unreliable because in 2006, after the events at issue in this case, the FDA adopted a new label for Sulindac that included both a hypersensitivity warning and a new SJS/TEN warning in its "Warnings" section. *See Bartlett*, 2010 DNH 112, at 15 n.6. She reasons that the FDA would not have approved "side-by-side redundant and duplicative warnings" and therefore must believe that -- contrary to Dr. Stern's opinion -- the hypersensitivity language in the earlier label did not adequately warn of SJS/TEN. But Bartlett has not presented any authority or evidence to support that proposition (which is just as speculative as Mutual's excluded testimony about FDA beliefs, see Part III.A.i, supra). There is nothing inherently illogical about repeating a safety warning, especially when one wants to emphasize a point.

And in any event, an expert's opinion need only be "based upon sufficient facts or data," Fed. R. Evid. 702(1), not perfectly consistent with every piece of available evidence. Emphasizing inconsistencies between an expert's opinions and the evidence, of course, is one of the principal purposes of expert cross-

examination. Bartlett's request to exclude Dr. Stern's testimony about the warning is denied.

x. Other NSAID side effects (Request 23)

The next issue is whether defense experts may testify about other NSAID side effects that Bartlett never suffered, such as gastrointestinal problems. Bartlett argues that such testimony is not relevant. But it is highly relevant to determining whether Sulindac's safety risks outweigh its medical benefits, making it an unreasonably dangerous product. *See, e.g., Price v. BIC Corp.*, 142 N.H. 386, 389 (1997) (noting that whether a product is unreasonably dangerous "is determined by the jury using a risk-utility balancing test"); *see also* Fed. R. Evid. 401, 402. The jury is not limited to considering only the side effects that Bartlett suffered. Bartlett's request to exclude such testimony is denied.

xi. Impact on FDA and industry (Requests 24-25)

Bartlett seeks to preclude Dr. Ehrreich from testifying that if generic drug manufacturers were each responsible for monitoring the safety of their drugs or strengthening their warnings, they would either have to raise prices or go out of business, and that the FDA would be over-burdened. This court has already ruled, as a matter of federal law, that generic manufacturers are indeed responsible for such safety surveillance, *see Bartlett*, 2010 DNH 112, at 29-31 (citing 21 C.F.R. § 314.80(b)), and for the content of their drugs' warnings, *see id.* at 9 n.4 (citing 21 C.F.R. § 201.57(e)). Mutual's experts may not suggest otherwise, either expressly or implicitly. To that extent, Bartlett's request is granted. *See* Fed. R. Evid. 403.

xii. Rebuttal of Bartlett's experts (Requests 26-28)

Bartlett argues that Dr. Ehrreich should not be allowed to criticize Bartlett's experts without first identifying the specific opinions with which he is disagreeing. She notes, for example, that Dr. Ehrreich's report launched a number of broadsides against her expert Dr. Randall Tackett's report, calling it "disturbing" and claiming to be "shocked and dismayed" by the amount of "misinformation." While Dr. Ehrreich's specific disagreements with Bartlett's experts and the basis of those disagreements are relevant and admissible evidence (assuming they have a proper foundation), the extent to which he is "disturbed" or "shocked and dismayed" by Bartlett's expert opinions and his pejorative characterizations of them are not. *See, e.g., United States v. Gonzalez-Maldonado*, 115 F.3d 9, 16 (1st Cir. 1997) (expert opinion on another witness's credibility "is ordinarily inadmissible pursuant to Rule 702"); *see also Ramirez v. Debs-Elias*, 407 F.3d 444, 447-49 (1st Cir. 2005). Bartlett's request to exclude such comments is granted.

Bartlett also argues that Dr. Ehrreich should be precluded from expressing two particular opinions that purport to rebut arguments that Bartlett's expert Dr. Tackett never made: one relating to so-called "black box" warnings, and the other relating to "due diligence." In both instances, Dr. Ehrreich's characterization of Dr. Tackett's opinion is not quite accurate. Dr. Tackett opined that Mutual should have advocated to the FDA for a "black-box" warning, not (as Dr. Ehrreich says) that Mutual should have implemented one unilaterally. And Dr. Tackett opined that Mutual should have conducted "due diligence"

before filing its initial application to manufacture Sulindac, not afterward (as Dr. Ehrreich says). Accordingly, this court grants Bartlett's request to exclude the inaccurate comments.

xiii. Industry standards of care (Request 31)

The next issue is whether Dr. Ehrreich may testify about standards of care within the pharmaceutical industry. Bartlett argues that such testimony should be prohibited unless her own experts may also testify about those standards, because Dr. Ehrreich is no more qualified than they are and because he provided no foundation for his opinions. But one party's failure to disclose an expert opinion on a given issue has little or no bearing on the admissibility of an adverse party's properly disclosed expert opinion evidence on that issue. *Cf. Adams v. J. Myers Builders*, 2009 DNH 181, 18 n.7. Whether Dr. Ehrreich's testimony may be admitted depends on his own qualifications, not on whether Bartlett's experts would be qualified to opine on the same issues.

As a pharmacologist who has held high-ranking jobs with the FDA and three major drug companies, Dr. Ehrreich is sufficiently qualified to testify about the standards of care within that industry. The foundation for that testimony is his own experience. *See, e.g., Forrestal*, 848 F.2d at 308 (affirming admission of doctor's expert testimony "based on his own knowledge and experience"); Fed. R. Evid. 702, advisory committee notes (2000) (noting that "the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience," which may be "the predominant, if not sole, basis for a great deal of reliable expert testimony"). Bartlett's request to exclude the testimony is denied.

xiv. Knowledge in medical community (Requests 32-35)

Bartlett argues that Dr. Stern should be precluded from testifying about what doctors generally know about SJS/TEN and their link to NSAIDs, because such testimony is speculative. Indeed, most courts have prohibited experts from testifying "about what all doctors generally consider in making prescription decisions" or about "what doctors generally think," unless the testimony is based on something more reliable than simply the expert's own experience as a doctor. *In re Diet Drugs*, 2000 WL 876900, at *11-12; *see also, e.g., In re Baycol*, 532 F. Supp. 2d at 1064; *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 277 (D.N.J. 2006); *In re Rezulin*, 309 F. Supp. 2d at 556. Since Dr. Stern has not identified a more reliable basis, Bartlett's request to exclude his testimony about what doctors generally know is granted. *See* Fed. R. Civ. P. 26(a)(2)(B); Fed. R. Evid. 702.

Dr. Stern may, however, testify about what a reasonable doctor *should* know about the link between NSAIDs and SJS/TEN and how a reasonable doctor would interpret Sulindac's safety warning. Such testimony is properly based on his experience as a professor of dermatology at Harvard Medical School, the chief of dermatology at a major Boston hospital, and the author of frequently cited articles on SJS/TEN and its link to NSAIDs. *See* Fed. R. Evid. 702; *First Marblehead*, 541 F.3d at 42 (upholding admission of a financial expert's testimony on how a reasonable investor would have analyzed stock options).

xv. Dr. Valuck (Request 36)

Bartlett seeks to exclude the testimony of another defense expert, pharmacology professor Dr. Robert Valuck, on the grounds that he was allegedly unprepared for his deposition. In particular, Bartlett emphasizes that Dr. Valuck erroneously stated that there were no Sulindac cases in a particular SJS/TEN study on which he opined, when in fact there was one such case. But this error (assuming it was one) resulted from a discrepancy between the print and online versions of the study. Dr. Valuck relied on the print version, which listed no Sulindac cases, whereas the online version listed one case. At his deposition, Dr. Valuck made clear that regardless of which version of the study is correct, it would not change his opinions.

Moreover, Bartlett has the ability to explore Dr. Valuck's error (if any) and its impact (if any) through cross-examination. "It is not the job of the court to insure that [expert testimony] is error-free" -- only that it has a sufficiently reliable foundation to satisfy Rule 702. *Southwire Co. v. J.P. Morgan Chase & Co.*, 528 F. Supp. 2d 908, 928 (W.D. Wis. 2007). Because Dr. Valuck's testimony about the SJS/TEN study appears, on this record, to have a proper foundation, Bartlett's request to exclude his testimony is denied.

xvi. Dr. Duffy (Request 37)

Finally, Bartlett argues that the testimony of Mutual's economic expert, Dr. Martin Duffy, should be excluded because he used the wrong figure for the cost of Bartlett's eye surgeries, thus rendering all of his computations unreliable. Mutual concedes that Dr. Duffy accidentally imported the wrong figure from the report of another defense expert, Dr. Jane Mattson, but

argues that Dr. Duffy's economic methodology is nonetheless reliable and that he should be allowed to testify using the corrected figures.

The general rule is that an expert's minor computational errors go to the weight of his testimony, rather than to its admissibility. *See, e.g., In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 530 (6th Cir. 2008); *see also In re Pharm. Indus. Avg. Wholesale Price Litig.*, 582 F.3d 156, 198 (1st Cir. 2009) (affirming admission of expert's testimony, even if he made "small" errors, because they did not affect "the reliability of his damages calculation"). Indeed, in a case involving this same expert, our court of appeals ruled that "whatever shortcomings existed in Duffy's calculations went to the weight, not the admissibility, of the testimony." *Cummings v. Std. Register Co.*, 265 F.3d 56, 65 (1st Cir. 2001). The same reasoning applies here. Dr. Duffy's error is unrelated to his methodology and easy for him to correct in his trial testimony (or to expose on cross- examination if he does not). Bartlett's request to exclude him from testifying is denied.

B. Mutual's motion

For its part, Mutual seeks to exclude or limit the testimony of Bartlett's expert witnesses on various grounds and also to exclude any expert testimony by Bartlett's treating physicians. This court will address each request in turn (identifying them by the section of Mutual's motion in which they were raised).

i. Failure to produce prior transcripts (Request A)

The first issue raised by Mutual's motion is whether three of Bartlett's experts should be precluded from

testifying because Bartlett failed to produce their prior deposition transcripts from other cases. This is essentially the mirror image of Bartlett's request to exclude one of Mutual's experts, Dr. Ehrreich, from testifying due to the late production of such a transcript. *See* Part III.A.ii, supra. This court denied Bartlett's request and, for similar reasons, denies Mutual's request as well. It is not clear from the record that Bartlett violated any disclosure obligations, and even if she did, exclusion would be an inappropriate sanction under the circumstances. *See* Fed. R. Civ. P. 37(c)(1) (providing for exclusion of expert witness for failure to disclose, "unless the failure was substantially justified or harmless").

ii. Similarity of experts' reports (Request A)

Mutual also argues that two of Bartlett's experts, pharmacologist Dr. Randall Tackett and burn surgeon Dr. Roger Salisbury, should be precluded from testifying because their reports contain such similar language that both reports must have been prepared by Bartlett's counsel, not by the experts themselves. Mutual argues that this is a violation of Fed. R. Civ. P 26(a)(2)(B), which requires each party's expert disclosures to "be accompanied by a written report ... prepared and signed by the witness." Bartlett argues, in response, that the reports are "99 percent textually distinct" and contain similar language in only a few areas where the two experts have shared experiences and expertise.

It is well established that "Rule 26(a)(2)(B) does not preclude counsel from providing assistance to experts in preparing reports, and indeed," in some complex cases, "this assistance may be needed." Fed. R. Civ. P 26(a)(2)(B), advisory committee notes (1993). The

report, however, must be based on the expert's prior substantive input, must reflect the testimony to be given by the witness, and must be signed by the witness. *Id.; see also United States v. Kalymon*, 541 F.3d 624, 637-38 (6th Cir. 2008); *Jenkins v. Bartlett*, 487 F.3d 482, 488 (7th Cir. 2007); *Crowley v. Chait*, 322 F Supp. 2d 530, 543 (D.N.J. 2004). Here, both experts' reports satisfy those requirements. Mutual's request to exclude their testimony under Rule 26(a)(2)(B) is denied.

iii. FDA regulations (Requests B.1-2)

The next issue raised by Mutual's motion is whether Bartlett's experts may testify about the meaning or applicability of FDA regulations and whether Mutual violated them. Such opinions appear frequently in Dr. Tackett's report and, to a lesser extent, in Dr. Salisbury's report.As discussed in Part III.A.i, *supra*, this court has "broad discretion to exclude expert opinion evidence about the law that would impinge on the roles of the judge and the jury." *Pelletier*, 470 F.3d 48, 54-55. Indeed, "[e]xpert testimony proffered solely to establish the meaning of a law is presumptively improper." *Mikutowicz*, 365 F.3d at 73.

Bartlett seems to believe that these principles apply only when the expert is wrong about the law, but that is not so. They apply even when the expert is right. *See, e.g., Nieves- Villanueva*, 133 F.3d at 100 ("the judge's expert knowledge of the law makes *any* such assistance at best cumulative, and at worst prejudicial") (emphasis added). Mutual's request to exclude such testimony is therefore granted. *See* Fed. R. Evid. 403.If Bartlett wants the jury to know what relevant FDA regulations require, she can propose

appropriate jury instructions. And if she wants to show the jury that Mutual violated them, she may do so by introducing evidence of Mutual's acts or failures to act, rather than conclusory opinions from her experts.

iv. Calling Mutual "negligent" (Request B.3)

A related issue is whether Bartlett's experts may describe Mutual's conduct as "negligent," which they repeatedly do in their expert reports. The general rule is that "testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact." Fed. R. Evid. 704(a). But that rule "does not vitiate the rule against expert opinion on questions of law." *Nieves-Villaneuva*, 133 F.3d at 100. Nor is it "a *carte blanche* for experts to substitute their views for matters well within the ken of the jury." *Dinco v. Dylex Ltd.*, 111 F.3d 964, 973 (1st Cir. 1997).

Courts have generally prohibited experts from using the term "negligent" to describe the defendant's conduct in a negligence case where the opposing party objects to it. *See* 4 *Weinstein's Federal Evidence* § 704.04[1], at 704-10 (2d ed. 1997) (citing *Andrews v. Metro N. Commuter R.R.*, 882 F.2d 705, 708 (2d Cir. 1989), and *Owen v. Kerr-McGee Corp.*, 698 F.2d 236, 240 (5th Cir. 1983)); *see also Persinger v. Norfolk & W. Ry. Co.*, 920 F.2d 1185, 1189 (4th Cir. 1990); *Shahid v. City of Detroit*, 889 F.2d 1543, 1547 (6th Cir. 1989). In light of Mutual's objection, Bartlett's experts may not use that term at trial to describe Mutual's conduct.

v. Qualifications (Request C)

Mutual also argues that Drs. Tackett and Salisbury lack sufficient expertise to testify about drug labeling

and FDA regulatory procedures, because neither has ever worked for the FDA or a drug manufacturer, and both misused FDA terminology at their depositions. "It is not required," however, "that experts be 'blue-ribbon practitioners' with optimal qualifications." *United States v. Vargas*, 471 F.3d 255, 262 (1st Cir. 2006) (affirming admission of fingerprint expert's testimony even though he could not answer certain questions about fingerprint characteristics). They need only be sufficiently "qualified ... by knowledge, skill, training, or education" to offer a reliable opinion. Fed. R. Evid. 702.

Dr. Tackett easily meets that standard. He has been a pharmacologist for more than 30 years, is a professor of pharmacology at the University of Georgia (where he has offered classes on FDA regulations and even conducted workshops for FDA employees), and has worked as a research investigator for various drug manufacturers. He also recently received a grant from a group of state Attorneys General to educate health care professionals about how to evaluate drug information. As another federal court recently concluded in allowing Dr. Tackett to testify, this "extensive experience" is enough to qualify him as an expert in this area. *Lofton v. McNeil Consumer & Specialty Pharms.*, 05-cv-1531, 2008 WL 4878066, at *9 (N.D. Tex. July 25, 2008).

Dr. Salisbury's qualifications make for a closer call. He is certainly well qualified to testify about SJS/TEN by virtue of his 36 years as a burn surgeon and his treatment of more than 400 patients with the disease. But his experience with drug labeling and the FDA is less extensive. His most significant credential is that he served as the lead author of a citizen's petition filed

with the FDA in 2005, after Bartlett's injuries, that resulted in the addition of a more explicit SJS/TEN warning to NSAID labels. *See Bartlett*, 2010 DNH 112, at 15 n.6. In his capacity as a professor of plastic surgery, he also "instructs his students [on] how to review [drug] labels ... so that they can appropriately communicate warnings to their patients." *Lofton*, 2008 WL 4878066, at *9.

While Dr. Salisbury may not be the optimal witness for this type of case, another federal court recently concluded that "his extensive practical experience with SJS/TEN patients and the efficacy of warning labels in the clinical setting" qualified him to testify about the adequacy of an NSAID's label. *Id.* This court agrees. Dr. Salisbury falls in the same camp as Mutual's corresponding expert Dr. Stern: both of them clearly know more about SJS/TEN than about drug labeling, but nevertheless have enough knowledge and experience to testify about the adequacy of Sulindac's safety warning as it relates to SJS/TEN. See Part III.A.ix, supra. Mutual's request to exclude Drs. Tackett and Salisbury from testifying due to a lack of qualifications is therefore denied.

vi. Mutual's ethics and motives (Requests D.1.a, D.2)

Mutual argues that Drs. Tackett and Salisbury should be precluded from testifying about the ethics or morality of Mutual's decisions or about Mutual's motive or state of mind in making them. Bartlett concedes, in response, that "other than state of mind as might plainly appear on a document or from deposition testimony," she will not "offer any opinions from Drs. Tackett or Salisbury on ethical obligations, state of mind, knowledge or intent." In light of that concession,

which the court interprets to cover motive as well, Mutual's request to exclude such testimony is moot. Any remaining objections in this area that Mutual may have can be made at trial.

vii. Generic drug labeling (Requests D.1.a, D.2)

Mutual also seeks to preclude Drs. Tackett and Salisbury from testifying that if Mutual had attempted to strengthen Sulindac's safety warning, the FDA would have approved those changes based on the information in the medical literature. Such testimony is indeed speculative on this record, for reasons that this court explained in its recent summary judgment ruling, *see Bartlett*, 2010 DNH 112, at 15, and in denying Bartlett's analogous request to exclude Mutual's experts from speculating that the FDA would *not* have allowed such changes. *See* Part III.A.i, *supra* (citing *In re Rezulin*, 309 F. Supp. 2d at 550, which excluded an expert's "speculation as to what FDA might have done in hypothetical circumstances"). As such, it lacks a sufficient foundation to satisfy Rule 702. Mutual's request to exclude such testimony is granted.

viii. Sulindac's risk of SJS/TEN (Request D.1.b)

Next, Mutual argues that Bartlett's experts should not be allowed to suggest that Sulindac carries a higher risk of SJS/TEN than other NSAIDs or other drugs. Mutual argues that such testimony is speculative, because the available evidence on that point -- including, in particular, the adverse event data reported by Maja Mockenhaupt et al., *The Risk of SJS and TEN Associated with NSAIDs: A Multinational Perspective*, 30 Journal of Rheumatology 2234-2240 (Oct. 2003)) -- is largely anecdotal and not statistically significant. But Bartlett's experts acknowledged the

limits of the data at their depositions, so this is really an issue for cross-examination, as opposed to outright exclusion. Moreover, a recently discovered draft of the study suggests that the data might be more extensive than is apparent from the published article. *See* document no. 251 (ordering supplemental depositions regarding that draft). Mutual's request to exclude testimony on this topic is denied.

Mutual also argues that Dr. Tackett should be prohibited from using information about Bactrim, another drug that Mutual manufactures and that has been linked to SJS/TEN, to support his opinion about what Mutual should have done with respect to Sulindac. Mutual argues that whether Bactrim creates a risk of SJS/TEN has no bearing on whether Sulindac creates such a risk and that, even it did, Mutual acquired Bactrim only one month or so before Bartlett filled her prescription. But those issues also go to weight, not admissibility. Mutual's request to exclude such testimony is denied.

ix. Treating physicians (Request E)

Finally, Mutual seeks to exclude Bartlett's treating physicians from offering any expert testimony at trial, since they did not prepare expert reports pursuant to Fed. R. Civ. P 26(a)(2)(B). Both parties agree, however, that "Rule 26(a)(2)(B) reports are not required as a prerequisite to a treating physician expressing opinions as to causation, diagnosis, [and] prognosis ... where they are based on the [plaintiff's] treatment," provided, as is the case with each doctor, that the witness has been properly designated as an expert under Rule 26(a)(2)(A). *Sprague v. Liberty Mut. Ins. Co.*, 177 F.R.D. 78, 81 (D.N.H. 1998) (Muirhead, M.J.); *see also Aumand v. Dartmouth Hitchcock Med.*

Ctr., 611 F. Supp. 2d 78, 87-89 (D.N.H. 2009). Bartlett has disavowed any intent to present testimony that goes beyond that scope.

To the extent that the parties may disagree about where the line should be drawn between "treatment" opinions and "non- treatment" opinions (which is not entirely clear from their briefing), those disagreements can be resolved at trial, in accordance with the basic principle set forth above. As a general matter, Bartlett's treating physicians may testify about whether Sulindac caused Bartlett's injuries, provided that they reached that conclusion in a reliable manner while examining and treating Bartlett. *See Sprague*, 177 F.R.D. at 81. But they should not be asked "hypothetical question[s]" about causation that "include[] information not learned during the course of treatment." *Vosburgh v. Bourassa*, 2008 DNH 133, at 7-8 (McAuliffe, C.J.). Such opinions would render them "witness[es] ... retained or specially employed to provide expert testimony in the case," requiring expert reports under Fed. R. Civ. P. 26(a)(2)(B), which were not produced.

IV. Conclusion

As set forth above, Bartlett's motion to exclude or limit Mutual's expert testimony[5] is GRANTED in part and DENIED in part. Mutual's corresponding motion to exclude or limit Bartlett's expert testimony[6] is also GRANTED in part and DENIED in part.

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5 Document no. 128.

6 Document no. 142.

SO ORDERED.

/s/Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: July 22, 2010

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v. Civil No. 08-cv-358-JL

Opinion No. 2010 DNH ___

Mutual Pharmaceutical Company, Inc.

SUMMARY ORDER

Bartlett has moved in limine to exclude various types of evidence from the upcoming trial. See L.R. 16.2 (b) (3). This court will address each of her motions in turn.

Motion #1; Generic drug pricing (doc. 185)

(a)-(b) Bartlett seeks to exclude evidence that generic drugs cost less than brand-name drugs. But such evidence is relevant background information, see Faigin v. Kelly, 184 F.3d 67, 81 (1st Cir. 1999) (calling it "well-settled that 'context' evidence generally is admissible"), and is not unfairly prejudicial to Bartlett. Her request is therefore denied. See Fed. R. Evid. 401-403.

(c)-(d) Bartlett seeks to exclude any suggestion by Mutual that a verdict against it in this case would result in higher drug prices. Mutual states that it has no intent to make any such suggestion. Bartlett's request is therefore granted. See Fed. R. Evid. 403.

(e)-(i) Bartlett seeks to exclude evidence that her doctor, instead of prescribing a particular manufacturer's version of Sulindac, allowed the

pharmacy to decide which version to use, and that the pharmacy chose Mutual's because of its lower cost. Evidence about the doctor's prescription decision is relevant background information, see Faigin, 184 F.3d at 81, and is not unfairly prejudicial to Bartlett, so her request to exclude it is denied. See Fed. R. Evid. 401-403. But evidence about the pharmacy's reason for choosing Mutual's version appears to be speculative, see Bartlett v. Mut. Pharm. Co., 2010 DNH 123, 12, see also Fed. R. Evid. 602 (permissible basis for fact witness testimony), 701 (permissible basis for lay opinion testimony) 703 (permissible basis for expert opinion testimony), and Mutual has not explained how it is relevant, see Fed. R. Evid. 401, 402. Bartlett's request to exclude it is therefore granted.

Motion #2: Bartlett's husband (doc. 186)

Bartlett seeks to exclude evidence of various facts regarding her husband and former co-plaintiff Greg Bartlett, including his problems with alcohol, his prior arrests and misdemeanor convictions, his incarceration and house arrest, his resulting resignation from work and continued unemployment, and his inability to care for his wife. The motion is granted in part. Such evidence is not admissible to impeach Bartlett or her husband. See Fed. R. Evid. 608, 609.

The evidence may, however, have some bearing on the amount of Bartlett's damages, in that her husband's legal troubles and job loss could be the source of some of her claimed emotional distress. See Fed. R. Evid. 401, 402. This court will determine at trial whether to allow some cross-examination in that regard and, if so, what limits are necessary to prevent unfair prejudice to Bartlett. See Fed. R. Evid. 403.

Motion #3: Collateral sources (doc. 188)

(a) Bartlett seeks to exclude evidence of any life or disability insurance, free or discounted transportation, or other government or charitable benefits that she has received as a result of her injuries. Her request is granted. All of the benefits at issue fall within the collateral source rule, which provides that "if a plaintiff is compensated in whole or part for his damages by some source independent of the tort-feasor, he is still permitted to make full recovery against [the tort-feasor]." Aumand v. Dartmouth Hitchcock Med. Ctr., 611 F. Supp. 2d 78, 90 (D.N.H. 2009) (quoting Moulton v. Groveton Papers Co., 114 N.H. 505, 509 (1974)). Thus, the probative value of such evidence is substantially outweighed by the risk of unfair prejudice. See Fed. R. Evid. 403.

(b) Bartlett asks this court to compel one of Mutual's experts, Jane Mattson, to acknowledge at trial that her life care plan for Bartlett omitted certain costs paid or provided by collateral sources. The request is denied. Bartlett is free to cross-examine Mattson about whether she omitted certain costs, and Mattson must answer without reference to collateral sources potentially available to pay those costs. But this court will not compel particular testimony. See id.

(c) Bartlett seeks to exclude evidence that her healthcare providers accepted less than face value in settlement of her medical bills. The request is granted. Such write-offs are also covered by the collateral source rule. See Reed v. Nat'l Council of Boy Scouts of Am., Inc., 2010 DNH 18, 18-28; Aumand, 611 F. Supp. 2d at 90-92. Thus, the probative value of such evidence is substantially outweighed by the risk of unfair prejudice. See Fed. R. Evid. 403.

(d) Although a defendant is normally allowed to challenge the reasonableness of medical bills, see Reed, 2010 DNH 18, at 28, Bartlett argues that Mutual should be prohibited from doing so because it failed to designate an expert on that issue. This request is denied. It is Bartlett's burden to prove damages, including that her medical expenses were reasonable. Mutual may, at the very least, use cross-examination to challenge the evidence that Bartlett presents (though it may not use evidence of the write-offs to do so, see Aumand, 611 F. Supp. 2d at 91-92). If Mutual attempts to introduce its own evidence of unreasonableness, this court will consider any objections Bartlett may have at that time.

(e) Bartlett also seeks to exclude evidence of her husband's past or future income. This request is subject to the same analysis as limine motion #2, supra.

(f) Finally, Bartlett seeks to exclude evidence that her disability insurer concluded, as of January 2008, that she was not totally disabled. Her request is granted, as that conclusion is hearsay, see Fed. R. Evid. 801(c), and Mutual has not argued that it is not hearsay, or for any hearsay exception. Moreover, the evidence is unfairly prejudicial to Bartlett, see Fed. R. Evid. 403, because it would reveal a collateral source of benefits and also could cause "the trial [to] deteriorate into a protracted and unproductive struggle" over the validity and significance of the disability insurer's decision. L'Etoile v.New Eng. Finish Sys., Inc., 575 F. Supp. 2d 331, 334 (D.N.H. 2008) (quoting Paolitto v. John Brown E. & C., Inc., 151 F.3d 60, 65 (2d Cir. 1998)).

Motion #4: Jury instructions (doc. 189)

This motion, which proposes two jury instructions, is taken under advisement and will be considered in connection with the parties' recent submissions of proposed jury instructions (see docs. 258 and 264).

Motion #5: Expert motion redux (doc. 190)

This motion simply reproduces Bartlett's motion to exclude or limit expert testimony (doc. 128), on which this court recently ruled. See Bartlett, 2010 DNH 123. It is therefore denied as moot.

Motion #6: Bartlett's doctor (doc. 191)

(a) Bartlett seeks to exclude any reference to certain comments that her treating physician, Dr. Tahsin Ergin, made to her counsel regarding an unsigned draft of his written declaration. The comments were somewhat critical of language drafted by Bartlett's counsel, calling a comparison of Sulindac to other NSAIDs "fairly selective" and requesting its removal. Bartlett's request is granted. The comments have little to no bearing on Dr. Ergin's credibility, which is Mutual's stated reason for using them. They have more to do with Mutual's counsel's credibility, which of course is not relevant, see Fed. R. Evid. 401, 402, and renders the comments unfairly prejudicial to Bartlett, see Fed. R. Evid. 403, to an extent that outweighs any other probative value they may have.[7]

(b) Bartlett seeks to exclude any references to Dr. Ergin's testimony about medical literature and data

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[7] In the highly unlikely event that Dr. Ergin's trial testimony creates the possibility that the comments become a vehicle for permissible impeachment, see Fed. R. Evid. 608(b), 613, Mutual's counsel shall request a sidebar or similar conference to proffer the statements before impeaching with or offering them.

that post-date his treatment of Bartlett. Her request is granted. Such testimony cannot be presented as expert opinion, because Dr. Ergin did not produce an expert report, see Fed. R. Civ. P. 26 (a) (2) (A), and thus may not answer "hypothetical questions" that require specialized knowledge and "include information not learned during the course of treatment." Bartlett, 2010 DNH 123, at 37 (quotation omitted). Nor can such testimony be presented as lay opinion, because post-treatment literature and data could not possibly have affected Dr. Ergin's decision to prescribe Sulindac to Bartlett and thus is not relevant for reasons independent of his expertise. See Fed. R. Evid. 701 (requiring lay opinion testimony to be "helpful to a clear understanding of the witness' testimony or the determination of a fact in issue" and "not based on ... specialized knowledge").

Motion #7: FDA's wishes (doc. 192)

This motion seeks to exclude any references to what the FDA or its personnel "want" from generic drug manufacturers, or what they "would or would not have approved, considered, or rejected." The motion is granted, as any such testimony would be speculative and unfairly prejudicial. See Bartlett, 2010 DNH 123, at 6-7, 34 (granting both parties' motions to exclude expert testimony of this sort); see also Fed. R. Evid. 602 (permissible basis for fact witness testimony), 701 (permissible basis for lay opinion testimony).

Motion #8: Bad luck (doc. 193)

(a) Bartlett seeks to exclude lay witnesses from attributing her injuries to "bad luck," "luck of the draw," or similar phrases. It is difficult to envision how or why this issue would arise at trial, as lay opinion of that sort obviously is not "helpful to a clear

understanding of the witness' testimony or the determination of a fact in issue." Fed. R. Evid. 701. Still, even if it does arise, any prejudice to Bartlett is likely to be minimal, since a lay witness has no authority on such matters. Cf. Bartlett, 2010 DNH 123, at 11 n.2. Bartlett's request is nonetheless granted under Rule 701.

(b) Bartlett also seeks to preclude lay witnesses from opining that they have no criticism of Mutual's actions. Her request is granted. Such testimony would not be "helpful to a clear understanding of the witness' testimony or the determination of a fact in issue" and thus is not permissible lay opinion. See Fed. R. Evid. 701.

Motion #9: Litigation history (doc. 194)

Bartlett seeks to exclude any references to her prior complaint in this case, prior parties that have been dismissed, or prior claims that have been dismissed. Since Mutual has no objection to this motion, it is granted. See Fed. R. Evid. 401-403; L'Etoile, 575 F. Supp. 2d at 339-40.

Motion #10: Bartlett's counsel (doc. 195)

Bartlett seeks to exclude various facts about her counsel and about other SJS/TEN litigation. Since Mutual has no objection to this motion, it is granted. See Fed. R. Evid. 401-403.

Motion #11; Good character (doc. 196)

(a)-(c) Bartlett seeks to exclude any testimony or argument that vouches for the good character of the FDA, Mutual, or their employees, and how hard-working they are. Mutual objects that such testimony is merely background information that should be permitted to help the jury put this case in context. But

Mutual can provide an adequate background without introducing impermissible character evidence of that sort. Bartlett's request is therefore granted. See Fed. R. Evid. 404(a), 608. This ruling is without prejudice, however, to being revisited should Bartlett "open the door" with evidence of the FDA's alleged lack of resources or capability. Cf. United States v. Fowler, 620 F. Supp. 2d 229, 233 (D.N.H. 2009) (noting that a party can "open[ ] the door to cross-examination on [otherwise inadmissible character] evidence by testifying about the subject on direct") (citing United States v. Balthazard, 360 F.3d 309, 317 (1st Cir. 2004)).

(d) Bartlett also seeks to exclude any references, first, to drugs other than Sulindac that Mutual manufactures, and second, to any good acts done by Mutual that are unrelated to the issues in this case (such as charitable donations or discounted drugs for the needy). The first request is denied, as the number and nature of the drugs that Mutual manufactures is relevant contextual information, at least within limits. But the second request is granted, as such "unrelated good acts" evidence, not justified by Mutual for any permissible reason under Rule of Evidence 404(b), is impermissible character evidence, see Fed. R. Evid. 404(a), 608, and otherwise is not relevant, see Fed. R. Evid. 401, 402.

Motion #12: Verdict's impact (doc. 197)

Bartlett seeks to exclude any references to how a verdict in her favor might impact the community, insurance costs, or the drug industry. Since Mutual has no objection to this motion, it is granted. See Fed. R. Evid. 403.

Motion #13: Others' health (doc. 198)

Bartlett seeks to exclude any references to the health of other persons, including the fact that one of Mutual's experts has suffered from cancer. Since Mutual has no objection to this motion, it is granted. See Fed. R. Evid. 401, 402. It should go without saying, of course, that this ruling does not limit either party from presenting evidence about the connection between Sulindac and SJS/TEN, notwithstanding the fact that such evidence may implicate SJS/TEN cases involving persons other than Bartlett.

Motion #14: Bartlett's history (doc. 200)

(a)-(b) Bartlett seeks to exclude evidence that she did not read Sulindac's label. Mutual argues that such evidence is relevant to show that the label is intended for the doctor, not the patient. But that is a point of law (known as the "learned intermediary" rule) on which both parties agree, not a disputed fact that Mutual needs to prove at trial. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112, 12 n.5. Moreover, the use of such evidence would be just as likely to suggest to the jury that Bartlett should have read the label, which is contrary to the law. Bartlett's request is therefore granted, see Fed. R. Evid. 401, 402, without prejudice to a showing by Mutual that the evidence is relevant for some other purpose.

(c) Bartlett seeks to prohibit any reference to her statement, made at her deposition, that doctors should be aware of Sulindac's link to SJS/TEN. She argues that such an opinion requires specialized knowledge, which she lacks. See Fed. R. Evid. 701, 702. Mutual argues, in response, that the statement is admissible as a party admission, notwithstanding Bartlett's lack of expertise. See Fed. R. Evid. 801(d)(2), advisory

committee notes (1972) (noting the "freedom which admissions have enjoyed ... from the restrictive influences of the opinion rule and the rule requiring firsthand knowledge"); but see 5 Weinstein's Federal Evidence § 801.30[4], at 801-55 (2d ed. 1997) (stating that party admissions "still must comply with other evidence rules").

Even assuming arguendo, however, that Bartlett's statement would be admissible as an admission, it is still "subject to exclusion under Rule 403 if its potential for unfair prejudice overwhelms its probative worth." Williams v. Drake, 146 F.3d 44, 48 (1st Cir. 1998) (citing 5 Weinstein, supra, 801.20[3], at 801-44). That is the case here. Bartlett's statement has little probative value, not only because of her lack of expertise, but also because a witness who actually has such expertise (Mutual's expert Dr. Robert Stern) will testify that reasonable doctors should be aware of the link between Sulindac and SJS/TEN, see Bartlett, 2010 DNH 123, at 24, and because Bartlett's prescribing physician has testified that he did, in fact, know of that link, see Bartlett, 2010 DNH 112, at 6. Given the statement's potential for unfair prejudice to Bartlett, her request to exclude it is granted. See Fed. R. Evid. 403.

(d)-(f) Bartlett seeks to exclude evidence that, in addition to the skin reactions and swallowing problems that she allegedly suffered as a result of taking Sulindac, she has suffered other, less serious skin reactions and swallowing problems at other times in her life. Mutual argues that such evidence is relevant because it suggests pre-existing conditions and hypersensitivity. Mutual has no expert testimony to support those theories. See Stevens v. Bangor &

Aroostook R.R. Co., 97 F.3d 594, 601 & n.7 (1st Cir. 1996) (emphasizing that "there is adequate expert testimony that an accident aggravated a pre-existing condition" and noting "the problem of ... admissibility" in the absence of such testimony). Without expert testimony, the evidence may have limited probative value. This court is not prepared to categorically exclude all such evidence at this point, but limits may be imposed at trial to prevent unfair prejudice to Bartlett. See Fed. R. Evid. 403.

(g) Bartlett seeks to exclude evidence that she previously took antibiotics for a dog bite. Mutual argues such evidence is relevant because the antibiotics carried a risk of SJS/TEN, as reflected on their warning label. Mutual will certainly be permitted to present evidence at trial that there are other drugs that cause SJS/TEN. Whatever limited relevance, if any, that Bartlett's personal consent to use of such drugs might have, however, is limited to instances where she was made aware of the SJS/TEN risk involved. Nothing in the record suggests, however, that Bartlett read that label or was aware of the SJS/TEN risk. The evidence thus has no little to no probative value and creates a risk of unfair prejudice to Bartlett. Her request is granted. See Fed. R. Evid. 403.

(h) Bartlett seeks to exclude evidence that her friend Linda Mailhot, or any other lay witness without medical training, knew that SJS/TEN were possible side effects of Sulindac. Her request is granted. Such evidence is purely anecdotal and, contrary to what Mutual argues, is not probative of what members in the medical community generally knew or should have known. See Fed. R. Evid. 401, 402. This ruling, of course, does not limit either party from presenting

evidence about whether Mutual or the FDA knew about Sulindac's link to SJS/TEN, regardless of whether their officials had medical training.

(i) Bartlett seeks to prevent Mutual from eliciting that some of her treating physicians formed no opinion about whether Sulindac caused her injuries, as established at their depositions. The request is denied. As this court previously explained, "Bartlett's treating physicians may testify about whether Sulindac caused Bartlett's injuries, provided that they reached that conclusion in a reliable manner while examining and treating Bartlett." Bartlett, 2010 DNH 123, at 36-37. Bartlett will not be unfairly prejudiced if some of her physicians testify that they never reached any conclusion on that subject. See Fed. R. Evid. 403.

Bartlett also seeks to exclude any undisclosed expert opinions about causation. That request is covered by this court's previous ruling on undisclosed expert opinions. See Bartlett, 2010 DNH 123, at 15-16.

(j) Finally, Bartlett seeks to exclude evidence that her husband's first son was born out of wedlock. Since Mutual concedes that such evidence is inadmissible, Bartlett's request is granted. See Fed. R. Evid. 401-403.

Motion #15: Uncalled witnesses (doc. 201)

Bartlett seeks to exclude any references by Mutual to witnesses not called by her to testify at trial, and any commentary on what their testimony might have been. "Under certain conditions, a party may argue that the jury should draw an adverse inference against the opposing party because of its failure to call a witness." Colon-Millin v. Sears Roebuck de P.R., Inc., 455 F.3d 30, 34 n.2 (1st Cir. 2006). Such an inference

may not be drawn, however, "unless the evidence shows that the witness is available to testify on behalf of the party, that the testimony of the witness would be relevant and noncumulative, and that the witness is not prejudiced against the nonproducing party." Id. (quoting United States v. Ariza-Ibarra, 651 F.2d 2, 15-16 (1st Cir. 1981)). Bartlett's motion is thus granted in part. Mutual may not comment on Bartlett's uncalled witnesses unless and until it lays a proper "missing witness" foundation and obtains this court's permission to do so. Any such request shall be made outside the presence of the jury.

Conclusion

As set forth above, this court GRANTS in part and DENIES in part some of Bartlett's motions in limine (docs. 185, 186, 188, 196, 200, and 201), GRANTS some of them (docs. 191, 192, 193, 194, 195, 197, 198), DENIES one of them as moot (doc. 190), and takes one under advisement (doc. 189).

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: July 23, 2010

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Civil No. 08-cv-358-JL
Opinion No. 2010 DNH 125

Mutual Pharmaceutical Company, Inc.

SUMMARY ORDER

Bartlett has moved in limine to exclude various types of evidence from the upcoming trial. See L.R. 16.2(b)(3). This court will address each of her motions in turn.

Motion #1: Generic drug pricing (doc. 185)

(a)-(b) Bartlett seeks to exclude evidence that generic drugs cost less than brand-name drugs. But such evidence is relevant background information, see Faigin v. Kelly, 184 F.3d 67, 81 (1st Cir. 1999) (calling it "well-settled that 'context' evidence generally is admissible"), and is not unfairly prejudicial to Bartlett. Her request is therefore denied. See Fed. R. Evid. 401-403.

(c)-(d) Bartlett seeks to exclude any suggestion by Mutual that a verdict against it in this case would result in higher drug prices. Mutual states that it has no intent to make any such suggestion. Bartlett's request is therefore granted. See Fed. R. Evid. 403.

(e)-(i) Bartlett seeks to exclude evidence that her doctor, instead of prescribing a particular

manufacturer's version of Sulindac, allowed the pharmacy to decide which version to use, and that the pharmacy chose Mutual's because of its lower cost. Evidence about the doctor's prescription decision is relevant background information, see Faigin, 184 F.3d at 81, and is not unfairly prejudicial to Bartlett, so her request to exclude it is denied. See Fed. R. Evid. 401-403. But evidence about the pharmacy's reason for choosing Mutual's version appears to be speculative, see Bartlett v. Mut. Pharm. Co., 2010 DNH 123, 12, see also Fed. R. Evid. 602 (permissible basis for fact witness testimony), 701 (permissible basis for lay opinion testimony) 703 (permissible basis for expert opinion testimony), and Mutual has not explained how it is relevant, see Fed. R. Evid. 401, 402. Bartlett's request to exclude it is therefore granted.

Motion #2: Bartlett's husband (doc. 186)

Bartlett seeks to exclude evidence of various facts regarding her husband and former co-plaintiff Greg Bartlett, including his problems with alcohol, his prior arrests and misdemeanor convictions, his incarceration and house arrest, his resulting resignation from work and continued unemployment, and his inability to care for his wife. The motion is granted in part. Such evidence is not admissible to impeach Bartlett or her husband. See Fed. R. Evid. 608, 609.

The evidence may, however, have some bearing on the amount of Bartlett's damages, in that her husband's legal troubles and job loss could be the source of some of her claimed emotional distress. See Fed. R. Evid. 401, 402. This court will determine at trial whether to allow some cross-examination in that regard and, if so, what limits are necessary to prevent unfair prejudice to Bartlett. See Fed. R. Evid. 403.

Motion #3: Collateral sources (doc. 188)

(a) Bartlett seeks to exclude evidence of any life or disability insurance, free or discounted transportation, or other government or charitable benefits that she has received as a result of her injuries. Her request is granted. All of the benefits at issue fall within the collateral source rule, which provides that "if a plaintiff is compensated in whole or part for his damages by some source independent of the tort-feasor, he is still permitted to make full recovery against [the tort-feasor]." Aumand v. Dartmouth Hitchcock Med. Ctr., 611 F. Supp. 2d 78, 90 (D.N.H. 2009) (quoting Moulton v. Groveton Papers Co., 114 N.H. 505, 509 (1974)). Thus, the probative value of such evidence is substantially outweighed by the risk of unfair prejudice. See Fed. R. Evid. 403.

(b) Bartlett asks this court to compel one of Mutual's experts, Jane Mattson, to acknowledge at trial that her life care plan for Bartlett omitted certain costs paid or provided by collateral sources. The request is denied. Bartlett is free to cross-examine Mattson about whether she omitted certain costs, and Mattson must answer without reference to collateral sources potentially available to pay those costs. But this court will not compel particular testimony. See id.

(c) Bartlett seeks to exclude evidence that her healthcare providers accepted less than face value in settlement of her medical bills. The request is granted. Such write-offs are also covered by the collateral source rule. See Reed v. Nat'l Council of Boy Scouts of Am., Inc., 2010 DNH 18, 18-28; Aumand, 611 F. Supp. 2d at 90-92. Thus, the probative value of such evidence is substantially outweighed by the risk of unfair prejudice. See Fed. R. Evid. 403.

(d) Although a defendant is normally allowed to challenge the reasonableness of medical bills, see Reed, 2010 DNH 18, at 28, Bartlett argues that Mutual should be prohibited from doing so because it failed to designate an expert on that issue. This request is denied. It is Bartlett's burden to prove damages, including that her medical expenses were reasonable. Mutual may, at the very least, use cross-examination to challenge the evidence that Bartlett presents (though it may not use evidence of the write-offs to do so, see Aumand, 611 F. Supp. 2d at 91-92). If Mutual attempts to introduce its own evidence of unreasonableness, this court will consider any objections Bartlett may have at that time.

(e) Bartlett also seeks to exclude evidence of her husband's past or future income. This request is subject to the same analysis as limine motion #2, supra.

(f) Finally, Bartlett seeks to exclude evidence that her disability insurer concluded, as of January 2008, that she was not totally disabled. Her request is granted, as that conclusion is hearsay, see Fed. R. Evid. 801(c), and Mutual has not argued that it is not hearsay, or for any hearsay exception. Moreover, the evidence is unfairly prejudicial to Bartlett, see Fed. R. Evid. 403, because it would reveal a collateral source of benefits and also could cause "the trial [to] deteriorate into a protracted and unproductive struggle" over the validity and significance of the disability insurer's decision. L'Etoile v. New Eng. Finish Sys., Inc., 575 F. Supp. 2d 331, 334 (D.N.H. 2008) (quoting Paolitto v. John Brown E. & C., Inc., 151 F.3d 60, 65 (2d Cir. 1998)).

Motion #4; Jury instructions (doc. 189)

This motion, which proposes two jury instructions, is taken under advisement and will be considered in connection with the parties' recent submissions of proposed jury instructions (see docs. 258 and 264).

Motion #5; Expert motion redux (doc. 190)

This motion simply reproduces Bartlett's motion to exclude or limit expert testimony (doc. 128), on which this court recently ruled. See Bartlett, 2010 DNH 123. It is therefore denied as moot.

Motion #6; Bartlett's doctor (doc. 191)

(a) Bartlett seeks to exclude any reference to certain comments that her treating physician, Dr. Tahsin Ergin, made to her counsel regarding an unsigned draft of his written declaration. The comments were somewhat critical of language drafted by Bartlett's counsel, calling a comparison of Sulindac to other NSAIDs "fairly selective" and requesting its removal. Bartlett's request is granted. The comments have little to no bearing on Dr. Ergin's credibility, which is Mutual's stated reason for using them. They have more to do with Bartlett's counsel's credibility, which of course is not relevant, see Fed. R. Evid. 401, 402, and renders the comments unfairly prejudicial to Bartlett, see Fed. R. Evid. 403, to an extent that outweighs any other probative value they may have.[8]

(b) Bartlett seeks to exclude any references to Dr. Ergin's testimony about medical literature and data

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[8] In the highly unlikely event that Dr. Ergin's trial testimony creates the possibility that the comments become a vehicle for permissible impeachment, see Fed. R. Evid. 608(b), 613, Mutual's counsel shall request a sidebar or similar conference to proffer the statements before impeaching with or offering them.

that post-date his treatment of Bartlett. Her request is granted. Such testimony cannot be presented as expert opinion, because Dr. Ergin did not produce an expert report, see Fed. R. Civ. P. 26 (a) (2) (A), and thus may not answer "hypothetical questions" that require specialized knowledge and "include information not learned during the course of treatment." Bartlett, 2010 DNH 123, at 37 (quotation omitted). Nor can such testimony be presented as lay opinion, because post-treatment literature and data could not possibly have affected Dr. Ergin's decision to prescribe Sulindac to Bartlett and thus is not relevant for reasons independent of his expertise. See Fed. R. Evid. 701 (requiring lay opinion testimony to be "helpful to a clear understanding of the witness' testimony or the determination of a fact in issue" and "not based on ... specialized knowledge").

Motion #7: FDA's wishes (doc. 192)

This motion seeks to exclude any references to what the FDA or its personnel "want" from generic drug manufacturers, or what they "would or would not have approved, considered, or rejected." The motion is granted, as any such testimony would be speculative and unfairly prejudicial. See Bartlett, 2010 DNH 123, at 6-7, 34 (granting both parties' motions to exclude expert testimony of this sort); see also Fed. R. Evid. 602 (permissible basis for fact witness testimony), 701 (permissible basis for lay opinion testimony).

Motion #8: Bad luck (doc. 193)

(a) Bartlett seeks to exclude lay witnesses from attributing her injuries to "bad luck," "luck of the draw," or similar phrases. It is difficult to envision how or why this issue would arise at trial, as lay opinion of that sort obviously is not "helpful to a clear

understanding of the witness' testimony or the determination of a fact in issue." Fed. R. Evid. 701. Still, even if it does arise, any prejudice to Bartlett is likely to be minimal, since a lay witness has no authority on such matters. Cf. Bartlett, 2010 DNH 123, at 11 n.2. Bartlett's request is nonetheless granted under Rule 701.

(b) Bartlett also seeks to preclude lay witnesses from opining that they have no criticism of Mutual's actions. Her request is granted. Such testimony would not be "helpful to a clear understanding of the witness' testimony or the determination of a fact in issue" and thus is not permissible lay opinion. See Fed. R. Evid. 701.

Motion #9: Litigation history (doc. 194)

Bartlett seeks to exclude any references to her prior complaint in this case, prior parties that have been dismissed, or prior claims that have been dismissed. Since Mutual has no objection to this motion, it is granted. See Fed. R. Evid. 401-403; L'Etoile, 575 F. Supp. 2d at 339-40.

Motion #10: Bartlett's counsel (doc. 195)

Bartlett seeks to exclude various facts about her counsel and about other SJS/TEN litigation. Since Mutual has no objection to this motion, it is granted. See Fed. R. Evid. 401-403.

Motion #11; Good character (doc. 196)

(a)-(c) Bartlett seeks to exclude any testimony or argument that vouches for the good character of the FDA, Mutual, or their employees, and how hard-working they are. Mutual objects that such testimony is merely background information that should be permitted to help the jury put this case in context. But

Mutual can provide an adequate background without introducing impermissible character evidence of that sort. Bartlett's request is therefore granted. See Fed. R. Evid. 404(a), 608. This ruling is without prejudice, however, to being revisited should Bartlett "open the door" with evidence of the FDA's alleged lack of resources or capability. Cf. United States v. Fowler, 620 F. Supp. 2d 229, 233 (D.N.H. 2009) (noting that a party can "open[ ] the door to cross-examination on [otherwise inadmissible character] evidence by testifying about the subject on direct") (citing United States v. Balthazard, 360 F.3d 309, 317 (1st Cir. 2004)).

(d) Bartlett also seeks to exclude any references, first, to drugs other than Sulindac that Mutual manufactures, and second, to any good acts done by Mutual that are unrelated to the issues in this case (such as charitable donations or discounted drugs for the needy). The first request is denied, as the number and nature of the drugs that Mutual manufactures is relevant contextual information, at least within limits. But the second request is granted, as such "unrelated good acts" evidence, not justified by Mutual for any permissible reason under Rule of Evidence 404(b), is impermissible character evidence, see Fed. R. Evid. 404(a), 608, and otherwise is not relevant, see Fed. R. Evid. 401, 402.

Motion #12: Verdict's impact (doc. 197)

Bartlett seeks to exclude any references to how a verdict in her favor might impact the community, insurance costs, or the drug industry. Since Mutual has no objection to this motion, it is granted. See Fed. R. Evid. 403.

Motion #13; Others' health (doc. 198)

Bartlett seeks to exclude any references to the health of other persons, including the fact that one of Mutual's experts has suffered from cancer. Since Mutual has no objection to this motion, it is granted. See Fed. R. Evid. 401, 402. It should go without saying, of course, that this ruling does not limit either party from presenting evidence about the connection between Sulindac and SJS/TEN, notwithstanding the fact that such evidence may implicate SJS/TEN cases involving persons other than Bartlett.

Motion #14; Bartlett's history (doc. 200)

(a)-(b) Bartlett seeks to exclude evidence that she did not read Sulindac's label. Mutual argues that such evidence is relevant to show that the label is intended for the doctor, not the patient. But that is a point of law (known as the "learned intermediary" rule) on which both parties agree, not a disputed fact that Mutual needs to prove at trial. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112, 12 n.5. Moreover, the use of such evidence would be just as likely to suggest to the jury that Bartlett should have read the label, which is contrary to the law. Bartlett's request is therefore granted, see Fed. R. Evid. 401, 402, without prejudice to a showing by Mutual that the evidence is relevant for some other purpose.

(c) Bartlett seeks to prohibit any reference to her statement, made at her deposition, that doctors should be aware of Sulindac's link to SJS/TEN. She argues that such an opinion requires specialized knowledge, which she lacks. See Fed. R. Evid. 701, 702. Mutual argues, in response, that the statement is admissible as a party admission, notwithstanding Bartlett's lack of expertise. See Fed. R. Evid. 801(d)(2), advisory

committee notes (1972) (noting the "freedom which admissions have enjoyed ... from the restrictive influences of the opinion rule and the rule requiring firsthand knowledge"); but see 5 Weinstein's Federal Evidence § 801.30[4], at 801-55 (2d ed. 1997) (stating that party admissions "still must comply with other evidence rules").

Even assuming arguendo, however, that Bartlett's statement would be admissible as an admission, it is still "subject to exclusion under Rule 403 if its potential for unfair prejudice overwhelms its probative worth." Williams v. Drake, 146 F.3d 44, 48 (1st Cir. 1998) (citing 5 Weinstein, supra, 801.20[3], at 801-44). That is the case here. Bartlett's statement has little probative value, not only because of her lack of expertise, but also because a witness who actually has such expertise (Mutual's expert Dr. Robert Stern) will testify that reasonable doctors should be aware of the link between Sulindac and SJS/TEN, see Bartlett, 2010 DNH 123, at 24, and because Bartlett's prescribing physician has testified that he did, in fact, know of that link, see Bartlett, 2010 DNH 112, at 6. Given the statement's potential for unfair prejudice to Bartlett, her request to exclude it is granted. See Fed. R. Evid. 403.

(d)-(f) Bartlett seeks to exclude evidence that, in addition to the skin reactions and swallowing problems that she allegedly suffered as a result of taking Sulindac, she has suffered other, less serious skin reactions and swallowing problems at other times in her life. Mutual argues that such evidence is relevant because it suggests pre-existing conditions and hypersensitivity. Mutual has no expert testimony to support those theories. See Stevens v. Bangor &

Aroostook R.R. Co., 97 F.3d 594, 601 & n.7 (1st Cir. 1996) (emphasizing that "there is adequate expert testimony that an accident aggravated a pre-existing condition" and noting "the problem of ... admissibility" in the absence of such testimony). Without expert testimony, the evidence may have limited probative value. This court is not prepared to categorically exclude all such evidence at this point, but limits may be imposed at trial to prevent unfair prejudice to Bartlett. See Fed. R. Evid. 403.

(g) Bartlett seeks to exclude evidence that she previously took antibiotics for a dog bite. Mutual argues such evidence is relevant because the antibiotics carried a risk of SJS/TEN, as reflected on their warning label. Mutual will certainly be permitted to present evidence at trial that there are other drugs that cause SJS/TEN. Whatever limited relevance, if any, that Bartlett's personal consent to use of such drugs might have, however, is limited to instances where she was made aware of the SJS/TEN risk involved. Nothing in the record suggests, however, that Bartlett read that label or was aware of the SJS/TEN risk. The evidence thus has no little to no probative value and creates a risk of unfair prejudice to Bartlett. Her request is granted. See Fed. R. Evid. 403.

(h) Bartlett seeks to exclude evidence that her friend Linda Mailhot, or any other lay witness without medical training, knew that SJS/TEN were possible side effects of Sulindac. Her request is granted. Such evidence is purely anecdotal and, contrary to what Mutual argues, is not probative of what members in the medical community generally knew or should have known. See Fed. R. Evid. 401, 402. This ruling, of course, does not limit either party from presenting

evidence about whether Mutual or the FDA knew about Sulindac's link to SJS/TEN, regardless of whether their officials had medical training.

(i) Bartlett seeks to prevent Mutual from eliciting that some of her treating physicians formed no opinion about whether Sulindac caused her injuries, as established at their depositions. The request is denied. As this court previously explained, "Bartlett's treating physicians may testify about whether Sulindac caused Bartlett's injuries, provided that they reached that conclusion in a reliable manner while examining and treating Bartlett." Bartlett, 2010 DNH 123, at 36-37. Bartlett will not be unfairly prejudiced if some of her physicians testify that they never reached any conclusion on that subject. See Fed. R. Evid. 403.

Bartlett also seeks to exclude any undisclosed expert opinions about causation. That request is covered by this court's previous ruling on undisclosed expert opinions. See Bartlett, 2010 DNH 123, at 15-16.

(j) Finally, Bartlett seeks to exclude evidence that her husband's first son was born out of wedlock. Since Mutual concedes that such evidence is inadmissible, Bartlett's request is granted. See Fed. R. Evid. 401-403.

Motion #15: Uncalled witnesses (doc. 201)

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may not be drawn, however, "unless the evidence shows that the witness is available to testify on behalf of the party, that the testimony of the witness would be relevant and noncumulative, and that the witness is not prejudiced against the nonproducing party." Id. (quoting United States v. Ariza-Ibarra, 651 F.2d 2, 15-16 (1st Cir. 1981)). Bartlett's motion is thus granted in part. Mutual may not comment on Bartlett's uncalled witnesses unless and until it lays a proper "missing witness" foundation and obtains this court's permission to do so. Any such request shall be made outside the presence of the jury.

Conclusion

As set forth above, this court GRANTS in part and DENIES in part some of Bartlett's motions in limine (docs. 185, 186, 188, 196, 200, and 201), GRANTS some of them (docs. 191, 192, 193, 194, 195, 197, 198), DENIES one of them as moot (doc. 190), and takes one under advisement (doc. 189).

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: July 26, 2010

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett
v.
Mutual Pharmaceutical
Company, Inc.

Civil No. 08-cv-358-JL
Opinion No. 2010 DNH 130

MEMORANDUM OPINION

Defendant Mutual Pharmaceutical Company has moved for reconsideration of this court's order denying Mutual's summary judgment motion in part and granting it in part. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112 ("Order").[1] Mutual argues that this court made a manifest error of law in ruling that Bartlett could prevail on her strict products liability claim by proving that the product at issue, the prescription drug Sulindac, was "defective because its safety risks outweigh its medical benefits, making it an unreasonably dangerous product," id. at 23 (footnote omitted), without having to prove that the product had some other "defect" in design.

While language in the New Hampshire Supreme Court's opinion in Buckingham v. R.J. Reynolds Tobacco Co., 142 N.H. 822 (1998), arguably supports Mutual's view, its subsequent decision in Vautour v. Body Masters Sports Industries, Inc., 147 N.H. 150 (2001), expressly holds that a plaintiff can prevail on a strict products liability claim by proving that a product

[1] Document no. 243.

was "unreasonably dangerous pursuant to the risk-utility balancing test," without also having to prove "a safer, alternative design," id. at 157. Mutual's motion does not address Vautour's holding and, indeed, barely mentions the case.

Accordingly, as fully explained infra, Mutual's motion to reconsider fails to demonstrate a "manifest error of fact or law," L.R. 7.2(e)," or, so far as the court is concerned, any error at all. The motion is therefore denied.

I. Background

The facts relevant to Mutual's motion for summary judgment are set forth throughout the Order and need not be repeated here. Essentially, Bartlett claims that she suffered a painful and life-threatening condition known as Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis, or "SJS/TEN," from taking Sulindac, a generic prescription drug manufactured by Mutual and prescribed by her doctor. In moving for summary judgment, Mutual argued principally that it adequately warned the doctor of the risk of SJS/TEN but that, even if it had not, any failure to warn was not the cause of Bartlett's injuries because her doctor admitted that he had not read Sulindac's warning label before prescribing it to her. Mutual argued that those flaws were fatal not only to Bartlett's failure-to-warn claims, but also to her strict products liability claim based on defective design, because "the primary allegation [she] relies upon to support [it] is [her] erroneous contention that Sulindac was defective because it lacked an adequate warning."

In support of her strict products liability claim, though, "Bartlett also alleges that Sulindac is defective because its safety risks outweigh its medical benefits,

making it an unreasonably dangerous product"--as this court ultimately observed in the Order. Thus, following oral argument on Mutual's summary judgment motion, the court ordered both parties to brief whether Bartlett's inability to prove causation on her failure-to-warn claims was also fatal to her strict products liability claim based on defective design.

Mutual maintained that it was, because "the New Hampshire Supreme Court would recognize that in actions involving pharmaceutical products, whether a product is defective in design turns on whether the product was accompanied by an inadequate warning." According to Mutual, that proposition followed from New Hampshire's embrace of comment k to the Restatement (Second) of Torts § 402A (1965), which, Mutual said, provides that "an unavoidably unsafe product is defective in design only if it is not accompanied by a proper warning." Because "[w]here a product design cannot be made safer, it is judged by the adequacy of its warnings," Mutual argued that a causal link between an allegedly inadequate warning and the plaintiff's injury was essential to a strict liability claim based on an unavoidably unsafe product.

This court accepted Mutual's premise--that New Hampshire would not hold the manufacturer of an important and unavoidably unsafe product strictly liable so long as it was accompanied by an adequate warning, see Order at 24-25--but rejected Mutual's conclusion that Bartlett's strict liability claim therefore failed for want of proof that the allegedly inadequate warning caused her injury, id. at 23-24. Instead, the court ruled, if Bartlett could prevail at trial on "whether Sulindac is unreasonably dangerous and whether that defective condition caused her injuries ...

Mutual might nonetheless be able to avoid liability for defective design if it can prove, as an affirmative defense, that Sulindac is unavoidably unsafe and had an adequate safety warning." Id. at 26. The court refused to enter summary judgment for Mutual based on that defense, however, because "the adequacy of Sulindac's safety warning is a matter of genuine dispute on this record." Id.

II. Analysis

As noted above, Mutual now argues that--quite apart from the adequacy of the warning--Bartlett's strict products liability claim fails because she cannot prove "a defect in the product." Proving that Sulindac's safety risks outweigh its medical benefits, making it unreasonably dangerous, is not enough, Mutual maintains.[2] Instead, Mutual says, Bartlett must also prove that Sulindac was "defective"--a concept that Mutual does not attempt to define, but which it insists cannot be proven here, because Sulindac "contains a single active ingredient" and therefore "cannot be made safer, as one would expect of a product containing a design defect."

There are a number of problems with this argument, but the first (and most glaring) is that the

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[2] In a footnote, Mutual suggests that Bartlett cannot prove even that, because her expert witnesses "do not compare the utility of Mutual's Sulindac to any other medications with respect to their ability to relieve pain and inflammation or to treat patients with ... any other condition" and "have not even addressed those benefits with respect to Sulindac itself." Because Mutual is not urging reconsideration on this point (and in fact did not even make this argument in support of its summary judgment motion), the court need not consider it here--but will do so at the appropriate point in the proceedings.

New Hampshire Supreme Court expressly rejected it in Vautour. There, the plaintiffs appealed from a directed verdict entered against them on their strict products liability claim, arguing that "the superior court erred by requiring them to prove an alternative design as an additional element in the case." 147 N.H. at 153. The defendant, however, urged the court "to adopt the Restatement (Third) of Torts § 2(b) (1998), which requires a plaintiff in a design defect case to prove that the risks of harm posed by the product could have been reduced or avoided by a reasonable alternative design." Id. at 154. The court declined, reasoning that "while proof an alternative design is relevant in a design defect case, it should be neither a controlling factor nor an essential element that should be proved in every case." Id. at 156. Instead, the court concluded, "the risk-utility test as currently applied protects the interests of both consumers and manufacturers in design defect cases." Id.

Under that test, the court explained, "a product is defective as designed 'if the magnitude of the danger outweighs the utility of the product.'" Id. at 154 (quoting William Prosser et al., Prosser and Keeton on the Law of Torts § 99, at 699 (5th ed. 1984)). Thus, because the "plaintiffs presented sufficient evidence that the [product at issue] was unreasonably dangerous pursuant to the risk-utility balancing test," the superior court "erroneously granted the defendant's motion for directed verdict upon the plaintiffs' strict liability, design defect claim. Under New Hampshire law, the plaintiffs' evidence was sufficient to establish a prima facie case." Id. at 157.

Mutual's argument flies in the face of this explicit holding, which the motion for reconsideration simply

ignores. Indeed, its only references to the case, express or implied, are in (1) a string citation with a parenthetical that describes the case as "involving [the] question of whether location of safety stops constituted a defective condition making equipment unreasonably dangerous" and (2) a footnote that, in what appears to be a tacit acknowledgment of Vautour, states that "[e]ven though plaintiff might not be required to establish that a safer alternative design exists, she must still prove that a defect exists." First, while Vautour certainly "involved" the question of the location of the safety stops on a leg press machine, the plaintiff presented no evidence that changing the location of the stops would have prevented his injury. 147 N.H. at 153. The New Hampshire Supreme Court, however, specifically ruled that no such evidence was necessary because, again, "the plaintiffs presented sufficient evidence that the leg press machine was unreasonably dangerous pursuant to the risk-utility test." Id. at 157. So Vautour requires the rejection of Mutual's argument that, even if Bartlett can adduce sufficient evidence that Sulindac's risks outweigh its benefits, her strict products liability claim still fails because she cannot prove that "a change in design would have avoided the injury" she suffered.

Second, Mutual does not attempt to reconcile its view that a plaintiff must prove that a product is "defective"--and cannot do so by proving only that its risks outweigh its benefits--with its concession that a plaintiff "need not prove that a safer alternative design exists." This cries out for an explanation as to how else a plaintiff proves that a product is defective in design. Mutual offers none. Vautour, however, does. Again, it expressly states that "a product is defective as designed if the magnitude of the danger outweighs the

utility of the product." 147 N.H. at 154 (quotation omitted). That is precisely how this court articulated Bartlett's strict liability claim in the summary judgment Order--"Sulindac is defective because its safety risks outweigh its medical risks." Order at 23. So Mutual's request for reconsideration rings hollow, particularly in the absence of any effort to meaningfully address the Vautour decision.[3]

In fairness to Mutual, the case on which it relies, Buckingham, did reject the argument that "'defect' is not a 'separate and distinct element of proof' from the 'unreasonably dangerous' element" in affirming the dismissal of a plaintiff's strict products liability claim against cigarette manufacturers. 142 N.H. at 825. The court reaffirmed that it recognizes "the tort of strict liability as set out in the Restatement (Second) of Torts § 402A, "which "imposes liability for selling 'any product in a defective condition unreasonably dangerous to the user or consumer' when the product causes injury to the user or consumer." Id. The court

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[3] This court also notes that Mutual's view appears to be inconsistent with comment *k* of the Restatement (Second) of Torts § 402A (1965), which allows manufacturers to avoid strict liability for defective design if they can prove that their product is important, unavoidably unsafe, and had an adequate warning. See Order at 24-26. There would be no need for comment *k* if, as Mutual argues, the fact that a product cannot be more safely designed is itself fatal to a strict products liability claim for defective design under New Hampshire law (regardless of the product's importance or the adequacy of its warning). Despite the fact that Mutual argued in moving for summary judgment that "New Hampshire courts evaluate a design defect claim involving a pharmaceutical product under comment *k*," its motion for reconsideration does not address this apparent inconsistency or mention comment *k*.

reasoned that if "a product is per se defective if it is unreasonably dangerous, then it would be redundant for section 402A to include both the terms 'defective' and 'unreasonably dangerous.'" Id. at 826. The court found further support for this reading in comment *i* to § 402A, which states that it applies "'only when the defective condition of the product makes it unreasonably dangerous to the user or consumer'" and "cites several products, such as tobacco, whiskey, and butter, that may be dangerous in their intended form ... but liability will not be imposed absent an additional ingredient which the ordinary consumer would not expect to be present." Id.

Thus, the court ruled, "because the plaintiff has failed to allege separately that cigarettes are 'defective' and 'unreasonably dangerous,' he has failed to state a claim upon which relief may be granted."[4] Id. Mutual, however, makes no attempt to reconcile this holding with the New Hampshire Supreme Court's subsequent decision in Vautour, which, again, specifically held that a product is defective if its risks outweigh its benefits so as to make it unreasonably dangerous. 147 N.H. at 154. A federal court exercising diversity jurisdiction over a state-law action, like this court here, "must apply the most recent statement of state law by the state's highest court." Vitkus v. Beatrice Co., 127 F.3d 936, 941-42 (10th Cir. 1997); see also, e.g., Brunner v. Hampson, 441 F.3d 457, 465 (6th Cir. 2006); Lamarque v. Mass. Indem. & Life Ins. Co., 794 F.2d 194, 196 (5th

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[4] To like effect is the decision by another judge of this court in Gianitsis v. Am. Brands, Inc., 685 F. Supp. 853, 856-57 (D.N.H. 1988) (Loughlin, D.J.), cited by both the New Hampshire Supreme Court in Buckingham and Mutual here. Like Buckingham, however, Gianitsis was decided prior to Vautour.

Cir. 1986); Middle Atl. Utils. Co. v. S.M. Dev. Corp., 392 F.2d 380, 384 (2d Cir. 1968); cf. Smith v. F.W. Morse & Co., 76 F.3d 413, 429 (1st Cir. 1996) (following the more "recently decided" New Hampshire Supreme Court case that "speaks directly to the question," rather than an older opinion). Insofar as Buckingham and Vautour are in conflict, then--a point on which, again, Mutual offers no argument at all[5]--this court must follow Vautour, as the New Hampshire Supreme Court's more recent articulation of its strict products liability rule. See also Kelleher v. Marvin Lumber & Cedar Co., 152 N.H. 813, 831 (2005) ("'a product is defective as designed if the magnitude of the danger outweighs the utility of the product'") (quoting Vautour, 147 N.H. at 154).[6]

III. Conclusion

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[5] Mutual does not argue, for example, that Buckingham, rather than Vautour, applies here.

[6] Moreover, even assuming (contrary to the express holding of Vautour, as followed in the Order and again here) that New Hampshire law required Bartlett to prove a safer alternative design, this court is skeptical of Mutual's argument, raised repeatedly throughout this litigation, that because Sulindac is a single "molecule and the molecule cannot be changed," no safer alternative design could possibly exist. See, e.g., Brown v. Super. Ct., 751 P.2d 470, 478 (Cal. 1988) (expressing "serious[ ] doubt" about such an argument, despite ruling as a matter of California public policy that drug manufacturers should be shielded from strict liability based on defective design). Even in such cases, a plaintiff "might be able to prove that other, less harmful drugs were available to prevent" the indicated condition (here, for example, other NSAIDs), so "the benefit of such alternate drugs could be weighed against the advantages of [the defendant's drug] in making the risk/benefit analysis." Id. That has been one of Bartlett's main arguments from the beginning.

New Hampshire law allows a plaintiff to recover in strict products liability by showing that a product is defective in design because its risks outweigh its benefits, and that the plaintiff suffered injury as a result. See Vautour, 147 N.H. at 154. As our court of appeals has observed, this test applies not just to "mass-produced items sold over the counter," but also to prescription drugs. Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 655 (1st Cir. 1981) (applying New Hampshire law). That is the law this court applied in the summary judgment Order, and will continue to apply here. For the foregoing reasons, Mutual's motion for reconsideration[7] is DENIED.

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: July 30, 2010

cc: Keith M. Jensen, Esq.
Bryan Ballew, Esq.
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[7] Document no. 263.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v. Civil No. 08-cv-00358-JL

Opinion No. 2010 DNH 131

Mutual Pharmaceutical Company, Inc.

SUMMARY ORDER

Mutual has moved in limine to exclude various types of evidence from the upcoming trial. See L.R. 16.2(b)(3). This court will address each of its motions in turn.

Motion #1: Adverse event reports

Mutual seeks to exclude evidence of adverse drug event reports received by the Food & Drug Administration ("FDA") or the World Health Organization ("WHO"), arguing that such reports are hearsay and that Bartlett has not demonstrated that the underlying cases involved sufficiently similar circumstances. This motion is granted in part. The reports are indeed hearsay "if offered to prove the truth of the matter[s] asserted" in them, i.e., that Sulindac caused SJS/TEN in a particular case. Fed. R. Evid. 801(c). Bartlett has not argued that they fall within any hearsay exception. Thus, the reports may not be offered for that purpose.

The reports are not hearsay, though, if offered to prove that the FDA was on notice of Sulindac's safety risks, or that Mutual should have been on notice of

such risks.[1] See Kelley v. Airborne Freight Corp., 140 F.3d 335, 346 (1st Cir. 1998); Golod v. Hoffman La Roche, 964 F. Supp. 841, 855 (S.D.N.Y. 1997) (adverse event "reports are not hearsay, because they are offered not as proof of the fact that [the drug] caused the reported blindness, but as evidence that [the defendant] was on notice of potentially serious optical side effects"). If Bartlett seeks to admit them for that purpose, Mutual may request a limiting instruction and/or seek other limits on their use (e.g., to require redactions, or allow only summaries rather than the reports themselves) to prevent any unfair prejudice. See Fed. R. Evid. 403.

This court disagrees, however, with Mutual's argument that the underlying cases need to be similar to this case "in all respects" for the reports to be admitted on the issue of notice. They need only be "substantially similar." Moulton v. Rival Co., 116 F.3d 22, 26-27 (1st Cir. 1997); McKinnon v. Skil Corp., 638 F.2d 270, 277 (1st Cir. 1981). Here, each of the reports concerns a patient who allegedly suffered SJS/TEN after taking Sulindac. That is a sufficient similarity to support their admission, at least for notice purposes. See Golod, 964 F. Supp. at 855.

Finally, Bartlett's experts may testify based on the reports if, and to the extent that, they are "reasonably relied upon by experts in the particular field,"

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[1] This court recently ordered the parties to brief the issue of whether Bartlett has trialworthy claims for negligence or enhanced compensatory damages and, if not, whether evidence of Mutual's alleged fault is admissible to support her claim for strict liability (see doc. 281). The court expresses no opinion on those issues here, other than to note that any pre-trial evidentiary rulings that reject challenges to evidence of Mutual's fault may need to be revisited after such briefing.

notwithstanding any hearsay problems. Fed. R. Evid. 703; see also In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 200 (S.D.N.Y. 2009) (allowing experts to testify based on such reports in another case involving a rare disease, but noting a split of authority on that issue). The reports themselves "need not be admissible in order for the [expert] opinion or inference to be admitted." Fed. R. Evid. 703. That does not mean, however, that Bartlett's experts may recite the contents of the reports or share copies with the jury. Id.

Motion #2: Other litigation

Mutual seeks to preclude references to other litigation involving Sulindac or other NSAIDs. Since Bartlett has no objection to this motion, it is granted. See Fed. R. Evid. 401-403; Bartlett v. Mut. Pharm. Co., 2010 DNH 125, 9 (granting a similar motion in limine filed by Bartlett). This ruling does not restrict either party from cross-examining each other's expert witnesses about their involvement in other cases, even if those cases involved Sulindac or other NSAIDs.

Motion #3: FDA's resources

Mutual seeks to exclude evidence of the FDA's alleged lack of resources and inability to monitor the safety of all drugs, arguing that such evidence has no probative value and is unfairly prejudicial. This motion is denied. Such evidence is relevant in determining how much weight, if any, should be given to the FDA's approval of Sulindac as safe and effective for its directed uses, and the FDA's approval of the drug's warning. See Fed. R. Evid. 401, 402. As a counterpoint to Mutual's evidence of those FDA approvals, the evidence is not unfairly prejudicial. See Fed. R. Evid. 403. Bartlett is reminded, however, that

her use of such evidence may "open the door" to contrary evidence from Mutual about the FDA's resources and abilities. See Bartlett, 2010 DNH 125, at 10.

Motion #4: Subsequent label changes

Mutual seeks to exclude evidence of certain changes to Sulindac's warning label that occurred after Bartlett's prescription, arguing that they are inadmissible as "subsequent remedial measures," see Fed. R. Evid. 407, and are unfairly prejudicial, see Fed. R. Evid. 403. The label changes resulted from a citizen's petition filed with the FDA by a group of doctors (including two of Bartlett's experts) in 2005. Although the petition related specifically to the drug ibuprofen and its risk of SJS/TEN, the FDA responded by requiring the manufacturers of all NSAIDs, including Sulindac, to insert a specific SJS/TEN warning into their drug labels. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112, 15 n.6 (quoting the warning).

Many courts have deemed evidence of post-prescription label changes inadmissible as "subsequent remedial measures" under Rule 407. See, e.g., Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 270-72 (5th Cir. 2002); DeLuryea v. Winthrop Labs., 697 F.2d 227, 229 (8th Cir. 1983); Werner v. Upjohn Co., 628 F.2d 848, 853 (4th Cir. 1980). This case is different, though, because the changes were mandated by the FDA for an entire class of drugs, not implemented by Mutual as a remedial measure specific to Sulindac. "Rule 407 applies only to subsequent remedial measures taken voluntarily by the defendant," Raymond v. Raymond Corp., 938 F.2d 1518, 1524 (1st Cir. 1991) (emphasis in original), and thus does not apply to broader

government-mandated measures of this sort. See, e.g., 2 Weinstein's Federal Evidence § 801.30[4], at 801-55 (2d ed. 1997) (citing Sabel v. Mead Johnson & Co., 737 F. Supp. 135, 141 (D. Mass. 1990), which admitted FDA letter recommending that manufacturer strengthen its drug label).

Since Rule 407 presents no barrier to admission of the post-prescription label changes, this court "must consider under Rule 403 whether [their] probative value is outweighed by the danger of unfair prejudice and confusion." Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 94 (2d Cir. 1980); see also Raymond, 938 F.2d at 1524. Of course, such changes can be highly probative of the label's adequacy, in that they may indicate an inaccuracy or omission in the prior label. But the danger is that they could be valued too highly by the jury, i.e., viewed as an implicit admission of inadequacy by the manufacturer. Some courts have excluded evidence of label changes on that basis. See, e.g., Gray v. Hoffman-La Roche, Inc., 82 Fed. Appx. 639, 646 (10th Cir. 2003); Lindsay, 637 F.2d at 94.

Again, however, this case is different. There is little risk here that the jury will view the label changes as an admission of inadequacy by Mutual, because they were mandated by the FDA and applied to all NSAIDs, not just Sulindac. Indeed, the changes may actually support Mutual's case as much as or more than Bartlett's, because the use of a class-wide warning "implies that all NSAIDs have a similar risk of SJS/TEN," Bartlett, 2010 DNH 112, at 15 n.6, and thus undermines Bartlett's claim that Sulindac has or may have a greater risk than other NSAIDs and that its warning should have said so. Moreover, Mutual has repeatedly argued that the FDA essentially "adopted"

the language from Sulindac's label, since it was the strongest of any NSAID's, and that the changes did not "materially improve" the prior warning (see, e.g., doc. 149, at 26).

Given that Mutual intends to use the FDA's approval of Sulindac's label as evidence of the label's adequacy (which is an element of Mutual's "comment k" defense, see Bartlett, 2010 DNH 112, at 25-26 (discussing Restatement (Second) of Torts § 402A, cmt. k (1965))), this court does not consider it unfairly prejudicial for Bartlett to counter with evidence that the FDA changed that label less than two years later, especially to the extent that the FDA relied on information available to Mutual at the time of Bartlett's prescription. One might even argue that it would be unfairly prejudicial to prevent Bartlett from responding in kind. In any event, "Rule 403 tilts the balance in favor of admission" in close cases. United States v. Whitney, 524 F.3d 134, 141 (1st Cir. 2008). Mutual's request to exclude evidence of the label changes is therefore denied.[2]

Motion #5: Surveillance firm

Mutual seeks to exclude evidence that after Bartlett's injuries it retained an outside firm to survey the medical literature for safety information relating to Sulindac and other drugs it manufactures. Mutual argues that such evidence is inadmissible as a subsequent remedial measure. See Fed. R. Evid. 407. Bartlett argues, in response, that such evidence is relevant to whether the outside firm should have been

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[2] Either party may, however, request a limiting instruction that neither the FDA's approval of the label, nor the fact that it required changes, is controlling on the issue of the label's adequacy.

retained earlier. But Rule 407 makes clear that subsequent remedial measures are "not admissible to prove negligence [or] culpable conduct." Mutual's motion is therefore granted.

Motion #6: Citizen's petition by Bartlett's experts

Mutual seeks to exclude evidence of the citizen's petition, discussed above in connection with motion #4, that resulted in post-prescription changes to Sulindac's label. This motion is denied, for the same reasons discussed above. One additional consideration here is that the petition's authors included two of Bartlett's experts. It is not entirely clear whether that authorship will operate to the benefit or detriment of either party. Nevertheless, Mutual may request a limiting instruction and/or seek other limits on the use of such evidence (e.g., redaction) to prevent any unfair prejudice.[3] See Fed. R. Evid. 403.

Motion #7: Citizen's petition by Mutual

Mutual seeks to preclude any reference to a citizen's petition that it filed with the FDA in 2008 requesting permission to manufacture and sell Sulindac in capsule form (as opposed to tablets). This motion is granted in part. The citizen's petition has no relevance as substantive evidence, because it does not involve the type of safety issues raised by Bartlett's defective design claims or the type of labeling issues raised by Mutual's "comment k" defense. See Fed. R. Evid. 401, 402. The petition may, however, have some bearing on the credibility of former FDA official and

[3] This court expresses no opinion on the hearsay arguments raised in Mutual's reply brief. Mutual may raise those objections at trial.

defense witness Robert Pollack, who signed it on Mutual's behalf. See Fed. R. Evid. 608(b).

Motion #8: Manufacturing and testing

Mutual seeks to preclude any reference to its manufacturing processes for Sulindac, the possibility of an alternative formulation of the drug, or product testing. This motion is granted. Bartlett concedes that she is no longer claiming that Sulindac had a manufacturing defect, or that Mutual could or should have formulated the drug differently, so evidence on those points is no longer relevant. See Fed. R. Evid. 401, 402. Mutual may, however, present evidence that Sulindac could not have been formulated differently, which is an element that it must prove to establish its "comment k" defense. See Bartlett, 2010 DNH 122, at 25-26.

As for product testing, Bartlett claims she is still pursuing a failure-to-test theory. But the basis for that theory is unclear. In her objection, Bartlett argues that Mutual "had an obligation to take action to ensure it was selling a safe drug" and that "skin patch testing or lymphocyte toxicity array tests to pre-challenge blood before anyone got this NSAID would have likely saved [her] eyes." But this court cannot find any support for that theory in her expert reports (or, for that matter, in the law).[4] Without expert testimony,

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[4] This is essentially just another "non-label" failure-to-warn theory, in that it suggests Mutual should have warned doctors and patients of the need for such testing. See Bartlett, 2010 DNH 112, at 21-22 (granting summary judgment on Bartlett's failure-to-warn claims and rejecting as speculative the similar theory "that Mutual should have launched an educational campaign to promote early monitoring of Sulindac's side effects").

references to such testing would only confuse or mislead the jury. See Fed. R. Evid. 403.

Motions #9: Unilateral label changes

Mutual seeks to preclude any suggestion that it had the right to strengthen Sulindac's safety warning unilaterally, which it argues is contrary to federal law. But this court has already ruled, as a matter of federal law, that Mutual did have that right. See Bartlett, 659 F. Supp. 2d at 279; Bartlett, 2010 DNH 112, at 38-41. The motion is therefore denied as moot. The court reiterates, however, that neither party may offer testimony on legal issues that fall within the province of the court, including this one. See Bartlett, 2010 DNH 123, at 5-6, 29-30.

Motion #10: Hypothetical FDA action

Mutual seeks to preclude any assertion that the FDA would have changed Sulindac's label or withdrawn it from the market if Mutual had given it certain information. This motion is granted, as any such assertion would be speculative and unfairly prejudicial for the reasons explained in this court's prior rulings. See Bartlett, 2010 DNH 123, at 6-7; docs. no. 271, 273; see also Fed. R. Evid. 602 (permissible basis for fact witness testimony), 701 (permissible basis for lay opinion testimony), and 703 (permissible basis for expert testimony).

Indeed, such an assertion appears to be contrary to what has actually happened. Sulindac remains on the market today with essentially the same label (except for the changes discussed in connection with motion #4, supra), even though the FDA has long been aware of the adverse event data and medical literature upon which Bartlett relies. See, e.g., Letter from Dr. Steven

Galson, Director of FDA's Center for Drug Evaluation & Research, to Bartlett's expert Dr. Roger Salisbury (June 22, 2006), doc. no. 215-4, at 2.

Motions #11 and #23: Legal testimony

Mutual seeks to preclude Bartlett from offering any testimony that interprets the law or expresses an opinion about whether Mutual violated it. This motion is granted, for reasons explained in this court's ruling on the parties' expert motions. See Bartlett, 2010 DNH 123, at 29-30.

Motions #12 to #15: Adequacy of label

Mutual seeks to preclude any testimony about the adequacy of Sulindac's warning label because there is no evidence that Bartlett or her prescribing doctor read or relied upon it. While that is true, and indeed is why this court granted summary judgment on Bartlett's failure-to-warn claims, see Bartlett, 2010 DNH 112, 13-18, the adequacy of the label remains relevant to this case in at least one respect, which is that Mutual's "comment k" defense depends on it.[5] See id. at 26. Mutual has not disclaimed that defense; rather, it seems to have filed this motion on the erroneous

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[5] Whether the label is also relevant to Bartlett's prima facie case is less clear. The New Hampshire Supreme Court has listed "the presence and efficacy of a warning" as one of "many possible factors" that "a jury must evaluate" in determining whether a product is unreasonably dangerous. See Vautour v. Body Masters Sports Indus., Inc., 147 N.H. 150, 154 (2001). But it has also said that "design defect and failure to warn claims are separate," with each providing an independent basis for strict products liability. LeBlanc v. Am. Honda Motor Co., 141 N.H. 579, 586 (1997). The question, then, is whether the label's adequacy can be considered in evaluating a design defect claim where, as here, the plaintiff's failure-to-warn claim fails for lack of causation. Since the parties have not briefed that issue, the court will not resolve it now.

assumption that the lack of reliance on Sulindac's label would defeat all of Bartlett's claims, rendering any defenses moot. Since that is not so, and since the label's adequacy remains at issue, Mutual's request to exclude all testimony on that subject is denied.

Mutual also seeks to preclude any suggestion that the Sulindac label failed to mention SJS/TEN in its "Warnings" section, despite mentioning it in the "Adverse Reactions" section. See id. at 4-5. Mutual argues that such a suggestion conflicts with the well-established rule that a drug label must be "read as a whole" to determine its adequacy. Id. at 10 (quoting Guevara v. Dorsey Labs., 845 F.2d 364, 366 (1st Cir. 1988)). This request, too, is denied. As explained in this court's summary judgment ruling, a warning can be inadequate not only "in factual content," but also "in expression of the facts, or in the method by which it is conveyed." Id. at 8-9 (quoting Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 657 (1st Cir. 1981)). On this record, there is a trialworthy question as to whether Sulindac's label should have warned of SJS/TEN more clearly and prominently, including in its "Warnings" section. Id. at 11. Both parties may present evidence on that issue.

Finally, Mutual seeks to preclude any suggestion that the Sulindac label failed to mention the potential complications of SJS/TEN (e.g., blindness, coma), arguing that a reasonable doctor would have known what that disease can entail. This request is denied for the same reasons discussed in the preceding paragraph. Mutual is free to present expert testimony regarding what a reasonable doctor would have known about SJS/TEN, see Bartlett, 2010 DNH 123, at 24-25, and to argue that Sulindac's label was sufficiently

detailed in light of that knowledge, but this court will not prohibit Bartlett from suggesting that the label should have been more detailed.

Motion #16: Sulindac's relative risk

Mutual seeks to preclude any suggestion that Sulindac carries a higher risk of SJS/TEN than other NSAIDs or other drugs, which it claims cannot be determined from the limited data available. This motion is denied as moot. The court already addressed this issue in its recent ruling on the parties' expert motions. See id. at 35 (rejecting Mutual's request for categorical exclusion of such testimony). Any objections that Mutual may have to specific testimony in this area will be considered at trial.

Motion #17: Bactrim

Mutual seeks to exclude evidence about Bactrim, another drug manufactured by Mutual that has been linked to SJS/TEN, arguing that such evidence is not relevant and is unfairly prejudicial. This motion is also denied as moot. The court addressed this issue, too, in its recent ruling on the parties' expert motions. See id. at 35-36 (rejecting Mutual's request to categorically exclude testimony about Bactrim by one of Bartlett's experts).[6] Any objections that Mutual may have to specific Bactrim evidence will be considered at trial.

Motion #18: Subsequent medical literature

Mutual seeks to preclude any reference to medical literature or FDA advisory committee documents that post-date Bartlett's prescription, arguing that such

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[6] But see note 1, supra (reserving judgment on whether Bartlett has trialworthy claims for negligence or enhanced compensatory damages and, if not, whether she can present evidence of Mutual's alleged fault).

evidence is not relevant and is unfairly prejudicial. This motion is granted in part. Bartlett may not use post-prescription materials to prove notice to Mutual or the FDA, since that is a chronological impossibility. See Fed. R. Evid. 401, 402. The evidence may, however, be relevant for other purposes,[7] and even if it constitutes hearsay, see Fed. R. Evid. 801(c), it may be a permissible basis for expert testimony, see Fed. R. Evid. 703. This court cannot make those determinations in the abstract, without reference to particular evidence. The remainder of Mutual's motion is therefore denied without prejudice to any objections that Mutual may raise at trial.

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[7] For example, although Bartlett must show "that [Sulindac's] unreasonably dangerous condition existed when the product was purchased," Thibault v. Sears, Roebuck & Co., 118 N.H. 802, 809 (1978), more recent safety information may shed light on the risk-utility analysis, since (based on the record presently before the court) Sulindac's design has not changed in the intervening period, nor have the designs of various alternative drugs, or the available technology. See, e.g., Brooks v. Beech Aircraft Corp., 902 P.2d 54, 63 (N.M. 1995) (unreasonable dangerousness "may be measured not only by the information available to the manufacturer at the time of design, but also by the information available to the trier of fact at the time of trial," at least in the absence of "unknowable design considerations"); Dart v. Wiebe Mfg., Inc., 709 P.2d 876, 880 (Ariz. 1985) (same).

While this court is aware of the intense scholarly debate over the use of post-purchase information as evidence in strict liability cases based on defective design, see 2 Louis R. Frumer & Melvin I. Friedman, Products Liability § 11.03[4][a], 11-88 to 11-89 (2010), such evidence is less concerning where, as here, the post-purchase information does not stray far afield from the pre-purchase information, either in time or content. The court notes, however, that limits may be imposed on such evidence at trial to prevent unfair prejudice, undue delay, or waste of time. See Fed. R. Evid. 403.

Motion #19: Prior medical literature

Mutual seeks to exclude evidence of an article regarding the link between NSAIDs and SJS/TEN, which it argues is hearsay and unreliable. See Maja Mockenhaupt et al., The Risk of SJS and TEN Associated with NSAIDs: A Multinational Perspective, 30 Journal of Rheumatology 2234-2240 (Oct. 2003). This motion is granted in part. The article is indeed hearsay "if offered to prove the truth of the matter[s] asserted" therein, see Fed. R. Evid. 801(c), and thus may not be offered for that purpose, except to the extent permitted by the "learned treatise" exception to the hearsay rule, see Fed. R. Evid. 803(18) (allowing limited use of such articles in cross-examination of expert witnesses), should Bartlett lay the appropriate foundation.

The article may, however, be offered to prove notice.[8] See Kelley, 140 F.3d at 346. Moreover, Bartlett's experts may testify based on the article, even if it is hearsay, since such articles are "reasonably relied upon by experts in the particular field." Fed. R. Evid. 703. The article itself "need not be admissible in order for the [expert] opinion or inference to be admitted." Id. Mutual's argument that the article is unreliable is belied by the fact that it was published in a prominent, peer- reviewed medical journal and that Mutual's own expert, Dr. Robert Stern, is one of the report's authors.[9]

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[8] But see note 1, supra (reserving judgment on whether Bartlett has trialworthy claims for negligence or enhanced compensatory damages and, if not, whether she can present evidence of Mutual's alleged fault).

[9] This court expresses no opinion on whether the recently discovered draft of the article (see doc. 230-2) is sufficiently

Motion #20: FDA reporting

Mutual seeks to exclude evidence that it failed to report to the FDA information from the medical literature regarding Sulindac's safety risks, arguing that it had no duty to do so and that such evidence therefore has no probative value and is unfairly prejudicial. This motion is denied. As explained in this court's summary judgment ruling, generic drug manufacturers are required by FDA regulations to survey the medical literature for adverse drug events associated with their drugs and to report such information to the FDA. See Bartlett, 2010 DNH 112, at 30-32 (interpreting 21 C.F.R. § 314.80(b)-(c)). While not establishing negligence per se, Mutual's failure to comply with those requirements is relevant evidence of negligence.[10] See id. at 35.

Motion #21: Patient medication guide

Mutual seeks to preclude any suggestion that it should have created a patient medication guide for Sulindac. This motion is granted. As explained in this court's summary judgment ruling, "a manufacturer's duty [under New Hampshire law] to warn of a drug's safety risks requires that the physician, not the patient, be warned." Bartlett, 2010 DNH 112, at 20. References to a patient medication guide, because they

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reliable to satisfy Rule 703. Since it was never published, and there is no indication (in the current record, anyway) that the FDA or Mutual was or should have been aware of it at the time of Bartlett's prescription, that draft clearly cannot be admitted to show notice.

[10] But see note 1, supra (reserving judgment on whether Bartlett has trialworthy claims for negligence or enhanced compensatory damages and, if not, whether she can present evidence of Mutual's alleged fault).

would imply a duty to warn the patient, would be confusing to the jury and unfairly prejudicial to Mutual. See Fed. R. Evid. 403.

Motion #22: Market withdrawal

Mutual seeks to preclude any suggestion that Sulindac should have been withdrawn from the market, arguing that withdrawal is not required under New Hampshire law (even for unreasonably dangerous products) and that any such suggestion would be unfairly prejudicial. But such a suggestion is implicit in every products liability case based on defective design, because the plaintiff must prove that the product's risks outweigh its benefits. Cf., e.g., Thibault, 118 N.H. at 807 ("a finding of liability for defective design could result in the removal of an entire product line from the market"). Thus, Mutual's claim of unfair prejudice is overstated.

Of course, Bartlett may not introduce evidence of what the law requires (if she even disagrees with Mutual on that point, which is unclear from her objection). To that extent, this motion is granted. See Bartlett, 2010 DNH 123, at 29-30; Fed. R. Evid. 403. Bartlett may, however, introduce evidence of industry practice, including the fact that other drugs linked to SJS/TEN have been withdrawn from the market, which is relevant to whether Sulindac was an unreasonably dangerous product. See Thibault, 118 N.H. at 814 (allowing evidence of industry practice to be admitted in a defective design case); see also Fed. R. Evid. 401, 402. To shed light on that evidence, she may also introduce expert testimony comparing Sulindac to those other drugs. The probative value of such evidence outweighs any prejudice to Mutual. See Fed. R. Evid. 403.

This court recognizes that there may be some tension between that evidence and what strict products liability requires, which is that manufacturers compensate consumers for the damage caused by unreasonably dangerous products, not necessarily that they remove such products from the market. See 5 Frumer & Friedman, supra, § 57.01[4], at 57-5 (noting that "almost all of the opinions which have addressed the issue have found that there is no common law duty to recall or retrofit" unreasonably dangerous products). Because of that tension, the court will entertain requests from Mutual for limiting instructions when such evidence is presented at trial and/or appropriate jury instructions at the close of the case.

Motion #24: Post-traumatic stress disorder

Mutual seeks to preclude psychologist Richard Goldberg from testifying that Bartlett had post-traumatic stress disorder, arguing that a psychologist is not qualified to make such a diagnosis under New Hampshire law. But the "question of whether expert testimony should be admitted or excluded" in a federal case "is a matter governed by federal, rather than state, law," even where the case involves state-law claims. Clark v. Heidrick, 150 F.3d 912, 914 (8th Cir. 1998); see also, e.g., Forrestal v. Magendantz, 848 F.2d 303, 305 (1st Cir. 1988); 29 Charles Alan Wright et al., Federal Practice and Procedure § 6263, at 202-03 (1997). Since Mutual invokes only state law and argues against the application of federal law, its motion is denied.[11]

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[11] Even under state law, Mutual's argument would be difficult to accept. See Baxter v. Temple, 157 N.H. 280 (2008) (deeming psychologist's expert testimony reliable and admissible where it included diagnosis of mental disorders).

Motion #25: Mutual's finances

Mutual seeks to preclude any reference to its income, net worth, or financial condition, arguing that such evidence is not relevant and is unfairly prejudicial. In products liability cases, "most states permit the introduction of the defendant's financial condition into evidence in order to help the jury determine the amount of punitive damages necessary to adequately punish the defendant." 2 Frumer & Friedman, supra, § 14.06[4], at 14-84. But punitive damages are not allowed in New Hampshire. See Stewart v. Bader, 154 N.H. 75, 88 (2006) ("No damages [including enhanced compensatory damages] are to be awarded as punishment to the defendant or as a warning and example to deter him and others from committing like offenses in the future."). Thus, evidence of Mutual's financial condition is not relevant for that purpose.

Bartlett has not shown that Mutual's financial condition is relevant for any other purpose. Mutual's motion is therefore granted. See Fed. R. Evid. 401-403; cf. Sawyer v. Boufford, 113 N.H. 627, 630 (1973) (vacating "an order requiring the defendant to disclose his financial worth" in a personal injury case because "his resources are not, and cannot be, an issue in the litigation"). This ruling is without prejudice, however, to being revisited should Mutual "open the door" by suggesting that it would have been too burdensome or costly for it to monitor Sulindac's safety risks.[12] See United States v. Fowler, 620 F. Supp. 2d 229, 233

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[12] But see note 1, supra (reserving judgment on whether Bartlett has trialworthy claims for negligence or enhanced compensatory damages and, if not, whether she can present evidence of Mutual's alleged fault).

(D.N.H. 2009) (noting that a party can "open[ ] the door to cross-examination on [otherwise inadmissible] evidence by testifying about the subject on direct") (citing United States v. Balthazard, 360 F.3d 309, 317 (1st Cir. 2004)).[13]

Motion #26: Treating physicians

Mutual seeks to preclude Bartlett's treating physicians from offering opinion testimony unless they formed their opinions during the course of Bartlett's treatment. This motion is denied as moot. The court already addressed this issue in its recent ruling on the parties' expert motions. See Bartlett, 2010 DNH 123, at 36-37; see also doc. 274 (applying that ruling in assessing the admissibility of deposition testimony by one of the physicians).

Motion #27: Liability insurance

Mutual seeks to preclude any reference to its insurance coverage. Since Bartlett has no objection to this motion, it is granted. See Fed. R. Evid. 411; Adams v. J. Meyers Builders, Inc., 671 F. Supp. 2d 262, 275 (D.N.H. 2009).

Motion #28: Litigation history

Mutual seeks to preclude any reference to certain motions it has filed in this case and their outcomes. Since Bartlett has no objection to this motion, it is granted. See Fed. R. Evid. 401-403; Bartlett, 2010

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[13] Bartlett also argues, in her objection, that she should be allowed to refer to Mutual's number of employees and its age as a company. But Mutual has not moved to exclude such evidence, which is relevant background information, see Faigin v. Kelly, 184 F.3d 67, 81 (1st Cir. 1999), and is not unfairly prejudicial to Mutual, see Fed. R. Evid. 403.

DNH 125, at 9 (granting similar motion in limine filed by Bartlett).

Motion #29: Deposition testimony

Mutual seeks to preclude the use of deposition testimony in lieu of live testimony, unless this court has deemed the deponent/witness "unavailable" for trial under Fed. R. Civ. P. 32(a)(4). See doc. 274 (deeming four of Bartlett's potential witnesses unavailable). Since Bartlett has not objected to this motion, it is granted.

Motion #30: "Golden rule" argument

Mutual seeks to preclude Bartlett from making a so-called "golden rule" argument, which invites the jury to put itself in the plaintiff's position. Since Bartlett has not objected to this motion, it is granted. See Forrestal, 848 F.2d at 309 (noting that such argument is "improper" and "universally condemned").

Motion #31: Witness sequestration

Mutual requests that witnesses be sequestered from the courtroom and prohibited from discussing the case with other witnesses during the trial. See Fed. R. Evid. 615; United States v. Magana, 127 F.3d 1, 5 (1st Cir. 1997) (noting that, in addition to sequestration, the court has discretion to "order that witnesses not converse with each other about the case"). This motion is granted without objection as to fact witnesses, including Bartlett's treating physicians, but not including Bartlett herself and Mutual's designated representative, who are exempted from sequestration by rule. See Fed. R. Evid. 615(1)-(2).

Bartlett argues that expert witnesses should also be exempted from sequestration because their "presence is ... essential to the presentation of the party's cause."

Fed. R. Evid. 615(3); see also id., advisory committee notes (1972) (stating that "essential" witnesses include "an expert needed to advise counsel in the management of the litigation"). Mutual has not argued otherwise. Since expert testimony is indeed essential to the parties' respective presentations, and since there is "little if any reason to sequester a witness who is to testify in an expert capacity only and not to the facts of the case,"[14] United States v. Lussier, 929 F.2d 25, 30 (1st Cir. 1991) (quoting Morvant v. Constr. Aggregates Corp., 570 F.2d 626, 629-30 (6th Cir. 1978)), the court exempts expert witnesses from its sequestration order.

Conclusion

As set forth above, Mutual's motions in limine[15] are granted in part and denied in part.

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: August 2, 2010

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[14] Indeed, Rule 703 expressly contemplates the presence of expert witnesses at trial, stating that an expert's opinions may be based on "facts or data . . . perceived by or made known to the expert at or before the hearing." See Fed. R. Evid. 703 (emphasis added).

[15] Document no. 205.

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v. Civil No. 08-cv-00358-JL

Mutual Pharmaceutical Company, Inc.

SUMMARY ORDER

Defendant Mutual Pharmaceutical Company has moved to bifurcate the trial, which is scheduled to begin next week, into separate liability and damage phases, see Fed. R. Civ. P. 42(b), and also to exclude from trial photographs and other images taken of plaintiff Karen Bartlett when she was suffering from Stevens-Johnson syndrome ("SJS") and toxic epidermal necrolysis ("TEN"), see Fed. R. Evid. 403; L.R. 16.2 (b)(3). For the reasons explained below, this court denies both requests, without prejudice to any objections that Mutual may raise at trial to the admissibility of specific images.

I. Timeliness

Both of Mutual's requests could have and should have been made much earlier. Mutual raised the bifurcation issue at the summary judgment hearing on June 1, 2010, and the court instructed it to file a motion. Mutual waited nearly two months to do so, filing this motion only three weeks before trial (when Bartlett's efforts to line up witnesses for trial were already underway and frequently discussed during hearings and telephone conferences). The challenge to SJS/TEN images, meanwhile, is really a motion in limine. The deadline for such motions was May 24, 2010. Although Mutual has not shown good cause for

delaying either request, the court will consider them nonetheless.

II. Bifurcation

Mutual requests that this court bifurcate the trial into separate liability and damage phases in order to avoid unfair prejudice and to promote judicial economy. See Fed. R. Civ. P. 42(b) ("For convenience, to avoid prejudice, or to expedite or economize, the court may order a separate trial of one or more separate issues"). The party seeking bifurcation bears the burden of proving that it will satisfy the objectives set forth in the rule. See 8 Moore's Federal Practice § 42.20[8], at 42-55 (3d ed. 2007). This court has broad discretion in determining whether bifurcation is appropriate. See, e.g., Lisa v. Fournier Marine Corp., 866 F.2d 530, 531 (1st Cir. 1989); 8 Moore's, supra, § 42.20[5], at 42-50.

Mutual argues, first, that it would be unfairly prejudicial for evidence of Bartlett's severe injuries to be presented to the jury before liability has been determined, because that could result in a verdict based on "horror and sympathy." But evidence of SJS/TEN's severity would be admissible at the liability phase even if the trial were bifurcated, because such evidence is highly relevant to whether Sulindac is unreasonably dangerous. See Fed. R. Evid. 401, 402. So Mutual's claim of unfair prejudice is overstated.

While it is true that a product's risks and benefits must be evaluated with reference to "the public as a whole," Vautour v. Body Masters Sports Indus., Inc., 147 N.H. 150, 154 (2001), not Bartlett in particular, some evidence of Bartlett's injuries would also be admissible at the liability phase to prove that Sulindac's defective condition caused those injuries.

Mutual indicated at the final pre-trial conference that it has no intent to challenge Bartlett's evidence on the issue of strict liability causation, but that it will require her to come forward with sufficient evidence, rather than stipulate to causation. And even if causation were conceded, some evidence of Bartlett's ordeal would still be admissible to "paint[ ] the backdrop" of the case. Faigin v. Kelly, 184 F.3d 67, 81 (1st Cir. 1999) (calling it "well-settled that 'context' evidence generally is admissible").

Mutual also argues that bifurcation could save time and resources (at least if Mutual prevails on liability) because the trial is expected to last four weeks and "there is no overlap between the evidence necessary to establish liability and the evidence to establish damages." Actually, there is significant overlap. Many of the damages witnesses, including four treating physicians and two of Bartlett's experts, are the same witnesses who will testify on causation. See Bartlett v. Mut. Pharm. Co., 2010 DNH 123, 36-37 (allowing treating physicians to express causation opinions if they were formed reliably during the course of Bartlett's treatment) (citing Sprague v. Liberty Mut. Ins. Co., 177 F.R.D. 78, 81 (D.N.H. 1998)). Thus, bifurcation would likely result in duplication of evidence. Moreover, it would force busy doctors from Boston hospitals to make two trips to New Hampshire for this trial, which is not the most efficient approach.

While bifurcation of liability and damages may be appropriate in some cases, it is "not the normal course of events, and a single trial will usually be more expedient and efficient." 8 Moore's, supra, § 42.20[4][a], at 42-46; see also Fed. R. Civ. P 42(b), advisory committee notes (1966) ("separation of issues for trial

is not to be routinely ordered"). After considering all of the factors set forth in Rule 42(b), the court does not believe that this case warrants a departure from the normal course. Mutual's request for bifurcation is denied.

III. Images of SJS/TEN

Mutual also requests that this court exclude from trial photographs and other images of Bartlett (or anyone else) suffering from SJS/TEN. Citing Federal Rule of Evidence 403, Mutual argues that the probative value of such images is substantially outweighed by the risk of unfair prejudice. But Mutual has not attached the relevant images to its motion. This court cannot conduct the Rule 403 analysis in the abstract, without seeing the images firsthand and without knowing whether they are cumulative of other evidence. Some evidence of SJS/TEN's severity, including images, will certainly be admissible. Mutual's request to exclude all such evidence is therefore denied, without prejudice to any objections that Mutual may raise at trial to the admissibility of specific images.

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: August 10, 2010

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v. Civil No. 08-cv-00358-JL

Mutual Pharmaceutical Company, Inc.

SUMMARY ORDER

This court recently ordered the parties, in advance of next week's trial, to brief (1) whether plaintiff Karen Bartlett has trialworthy claims for negligence or enhanced compensatory damages,[1] and (2) whether the defendant Mutual Pharmaceutical Company has sufficient evidence to support its affirmative defenses based on the allegedly culpable conduct of Bartlett or her doctor, Tahsin Ergin.[2] After reviewing the parties' briefs and the evidence proffered in support of those claims and defenses, this court concludes that none of them raises a genuine issue of material fact. See Fed. R. Civ. P. 56(c)(2). Mutual is therefore granted judgment as a matter of law on Bartlett's claims for negligence and enhanced compensatory damages, and Bartlett is granted judgment as a matter of law on Mutual's defenses based on the conduct of Bartlett and Dr. Ergin (specifically, the defenses of comparative negligence, apportionment, plaintiff's

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1 Document no. 281.

2 Document no. 296.

misconduct/failure to follow instructions, and superseding cause).

"It is without question that district courts, in appropriate circumstances, are entitled to enter summary judgment sua sponte." P.R. Elec. Power Auth. v. Action Refund, 515 F.3d 57, 64 (1st Cir. 2008). To guard against any unfairness to the parties, our court of appeals "has required two conditions prior to the district court's exercise of such a right": (1) "the discovery process must be sufficiently advanced that the parties have enjoyed a reasonable opportunity to glean material facts," and (2) "the district court must provide the targeted party with appropriate notice and a chance to present its evidence on the essential elements of the claim or defense." Id. at 64-65. Both of those conditions have been met here: the discovery process is over, and this court gave both parties notice and an opportunity to present their evidence.[3]

Given that the trial is scheduled to begin on Monday, the court likely will not be able to provide a more detailed order explaining this ruling until after the trial has begun. But such an order is forthcoming. To provide a brief explanation now, Bartlett's negligence claim is largely an improper attempt to revive her failure-to-warn claims, on which this court already granted summary judgment. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112, 22. And to the extent that her claim is based on conduct other than failure-to-warn, Bartlett has not presented sufficient evidence to establish causation. Since her claim for enhanced

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[3] In addition to the briefing mentioned above, this court discussed its concerns about these claims and defenses with the parties during the final pre-trial conference. See documents no. 301, 302.

compensatory damages is based on that same conduct, it also fails for lack of causation (regardless of whether she prevails on her strict liability claim). Mutual, in turn, has not presented the expert testimony necessary to establish that Bartlett's conduct caused or contributed to her injuries, or that Dr. Ergin breached his professional standard of care in a way that caused or contributed to Bartlett's injuries (even if one counts the testimony of Bartlett's experts).

For purposes of orienting the parties for trial, the court views the following claim and defenses as the only ones remaining in the case: Bartlett's claim of strict liability based on defective design, see id. at 22-26; Mutual's "comment k" or "unavoidably unsafe" defense, see id. at 24-26 (citing Restatement (Second) of Torts § 402A, cmt. k (1965)); and Mutual's "state of the art" defense, see N.H. Rev. Stat. § 507:8-g.[4] Mutual shall notify the court forthwith if it does not wish to pursue either of those defenses at trial.[5]

This court will make relevancy determinations at trial solely with reference to that remaining claim and

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[4] As discussed at the final pre-trial conference, the court does not view Mutual's invocation of the "learned intermediary doctrine" and "industry standards" as true defenses, but rather as legal principles relevant to other claims and defenses.

[5] To the extent that it may impact Mutual's decision on whether to pursue the "state of the art" defense, the court notes that it intends to give a jury instruction that directly tracks the language of the statute. See N.H. Rev. Stat. § 507:8-g. Consistent with the statute and this court's earlier rulings, the instruction will also set forth the procedures required by the Food & Drug Administration ("FDA") for surveying the medical literature, see Bartlett, 2010 DNH 112, at 30-32, so that the jury can analyze whether Sulindac's risks were discoverable using those procedures. If Mutual withdraws the defense, then those procedures will no longer be relevant and thus will not be presented to the jury.

defenses, see Fed. R. Evid. 401, 402, which may require revisiting some of the earlier limine rulings deeming evidence relevant and admissible to support Bartlett's claims for negligence and enhanced compensatory damages or Mutual's stricken defenses. See Bartlett v. Mut. Pharm. Co., 2010 DNH 131, 2 n.1.

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: August 11, 2010

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Mutual Pharmaceutical Company, Inc.

Civil No. 08-cv-00358-JL

SUMMARY ORDER

Plaintiff Karen Bartlett's motion in limine seeking to exclude from trial any evidence that her doctor Tahsin Ergin failed to read Sulindac's warning label and/or failed to warn her of the drug's safety risks (document no. 261) is GRANTED as to parts (a) and (b), but DENIED as to part (c). Such evidence was originally relevant to Bartlett's failure-to-warn claims and to defendant Mutual Pharmaceutical Company's apportionment and superseding cause defenses, but this court recently granted summary judgment on those claims and defenses. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112, 11-22 (failure-to-warn claims); document no. 329 (Mutual's defenses). The evidence is not relevant to any other claim or defense remaining in the case. See Fed. R. Evid. 401, 402. Bartlett's request to exclude it is therefore granted.

Since Bartlett has notified the court that she no longer intends to call Dr. Ergin as a witness (document no. 334), her request that she be allowed to ask certain warning-related questions of him during direct examination without "opening the door" to cross-examination by Mutual on the matters referenced above is denied as moot.

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: August 12, 2010

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v. Civil No. 08-cv-00358-JL

Mutual Pharmaceutical Company, Inc.

SUMMARY ORDER

Defendant Mutual Pharmaceutical Company has moved for reconsideration of this court's order denying Mutual's earlier motion for reconsideration of this court's summary judgment ruling. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112 (summary judgment ruling); Bartlett v. Mut. Pharm. Co., 2010 DNH 130 (denying Mutual's first motion for reconsideration). For the reasons discussed at length in those orders, at the final pre-trial conference (see documents no. 301 and 302), and below, Mutual's motion is denied.

Although Mutual claims that "[m]erely because a product is [unreasonably] dangerous does not, under New Hampshire law, mean it is defective," the two most recent decisions from the New Hampshire Supreme Court on this point expressly state that "a product is defective as designed if the magnitude of the danger outweighs the utility of the product." Vautour v. Body Masters Sports Indus., Inc., 147 N.H. 150, 154 (2001) (quoting William Prosser et al., Prosser and Keeton on the Law of Torts § 99, at 699 & n.30 (5th ed. 1984)); Kelleher v. Marvin Lumber & Cedar Co., 152 N.H. 813, 831 (2005). This court is bound to follow the plain meaning of those statements, notwithstanding any language arguably to the contrary in the earlier case of Buckingham v. R.J. Reynolds Tobacco Co., 142 N.H. 822 (1998).

Moreover, Vautour and Kelleher expressly state that "the plaintiff is not required to present evidence of a safer alternative design" in a defective design case. Kelleher, 152 N.H. at 831 (2005); see also Vautour, 147 N.H. at 156. The question remains as to how, under Mutual's reading of Buckingham and Vautour/Kelleher, a plaintiff could prove a "defect" without proving some alternative design. In its motion, Mutual gave a circular answer: that "to respond to the Court's call for an explanation, a plaintiff may prove a defect in a product's design by producing evidence that a particular aspect of the product is defective." When pressed at the pre-trial conference, Mutual gave an unhelpful answer: "there has to be an alternative [design]; you just don't have to prove up the alternative." Proof, though, is all that counts here.

Vautour and Kelleher provide a much simpler answer to this court's question: a plaintiff may prove a defect by showing that the product's risks outweigh its benefits, making it unreasonably dangerous to consumers. That is the law this court followed in its earlier orders, and will continue to follow here and at the upcoming trial.[1]

As a final note, Mutual acknowledged at the pre-trial conference that its reading of Buckingham and

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[1]Moreover, even if Bartlett had to prove an alternative design, this court is skeptical of Mutual's argument that she cannot do so by showing that other non-steroidal anti-inflammatory drugs ("NSAIDs") offer the same benefits as Sulindac with less or no risk of Stevens-Johnson syndrome/toxic epidermal necrolysis ("SJS/TEN"). See Bartlett, 2010 DNH 130, at 11 n.6. That additional, unnecessary, and unexpected risk of SJS/TEN is, in Vautour's terminology, what Bartlett alleges is "wrong" with the product. 142 N.H. at 826.

Vautour/Kelleher would have the practical effect of immunizing nearly all drug manufacturers from strict liability, no matter how dangerous the drug, no matter how minimal its benefits, no matter what its warning said (unless the prescribing doctor read and relied on the warning), and even if other, similar drugs offer the same benefits with less risk.[2] While that result may be defensible on public policy grounds, see Brown v. Super. Ct., 751 P.2d 470 (Cal. 1988), it is not this court's place to announce it as the public policy of New Hampshire, especially in the face of Vautour and Kelleher.

Because Mutual has not demonstrated that this court's order denying its earlier motion for reconsideration "was based on a manifest error of fact or law," L.R. 7.2(e), Mutual's motion for reconsideration[3] is DENIED.

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: August 12, 2010

cc: Keith M. Jensen, Esq.
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[2] The only exception, in Mutual's view, would be drugs whose dosage or other design features could be altered to reduce or eliminate the unreasonable danger, as in Brochu v. Ortho. Pharm. Corp., 642 F.2d 652 (1st Cir. 1981).

[3] Document No. 293.

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Civil No. 08-cv-00358-JL
Opinion No. 2010 DNH 148

Mutual Pharmaceutical Company, Inc.

MEMORANDUM ORDER

This products liability case, which arises from injuries allegedly caused by the prescription drug Sulindac, is scheduled to begin trial next week. In advance of trial, this court ordered the parties to brief whether the defendant Mutual Pharmaceutical Company has sufficient evidence to support its affirmative defenses based on (1) plaintiff Karen Bartlett's failure to stop taking the drug Sulindac and/or to seek medical care as soon as she began feeling sick; and (2) her doctor Tahsin Ergin's failure to read Sulindac's warning label and/or to warn Bartlett of the drug's safety risks. After reviewing the parties' submissions, this court concludes that Mutual (which has not designated an expert to explain how any of those failures caused or contributed to Bartlett's injuries) does not have sufficient evidence to support those defenses and accordingly strikes them from the case.[1]

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[1] The court initially announced this ruling during a conference call with the parties on August 11, 2010, and in a summary order later that day, see document no. 329. This order sets forth the court's reasoning in greater detail.

I. Applicable legal standard

"It is without question that district courts, in appropriate circumstances, are entitled to enter summary judgment sua sponte." P.R. Elec. Power Auth. v. Action Refund, 515 F.3d 57, 64 (1st Cir. 2008). To guard against any unfairness to the parties, our court of appeals has "required two conditions prior to the district court's exercise of such a right:" (1) "the discovery process must be sufficiently advanced that the parties have enjoyed a reasonable opportunity to glean the material facts," and (2) "the district court must provide the targeted party appropriate notice and a chance to present its evidence on the essential elements of the claim or defense." Id. at 64-65. Both of those conditions have been met here: the discovery process is over, and this court gave Mutual notice and an opportunity to present evidence on its defenses.[2] This court will therefore evaluate those defenses as it would in the context of a summary judgment motion filed by Bartlett.[3]

Summary judgment is appropriate where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine

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[2] See documents no. 296 (order), 322 (Mutual's brief), and 326 (Bartlett's brief). In addition to the briefing, this court discussed its concerns about the defenses with the parties during the final pre-trial conference. See document no. 301, at 29-42.

[3] Of course, this court would also have the authority at trial to refuse to instruct the jury on defenses for which Mutual has not presented sufficient evidence. See Fed. R. Civ. P. 50 (a)(1). Mutual would not fare any better then, because (as explained infra) it lacks sufficient expert testimony to support its defenses, and the expert disclosure rules prevent it from remedying that defect by introducing new expert opinions at trial. See Fed. R. Civ. P. 26 (a)(2)(B).

issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56 (c)(2). An issue is "genuine" if it could reasonably be resolved in either party's favor at trial, and "material" if it could sway the outcome under applicable law. Mulvihill v. Top-Flite Golf Co., 335 F.3d 15, 19 (1st Cir. 2003). In making that determination, the "court must scrutinize the record in the light most flattering to the party opposing the motion, indulging all reasonable inferences in that party's favor." Id. The following factual summary is consistent with that approach.

II. Background[4]

In December 2004, Bartlett sought medical treatment for pain in her right shoulder. Her doctor, Tahsin Ergin, prescribed a non-steroidal anti-inflammatory drug ("NSAID") called Clinoril. Dr. Ergin did not read the drug's label before prescribing it. Even without reading the label, Dr. Ergin knew from his medical background that the drug could cause a serious and potentially fatal skin disease known as Stevens-Johnson syndrome ("SJS") or toxic epidermal necrolysis ("TEN"). But it was not his usual practice to discuss that risk with patients, and he did not do so with Bartlett. Instead, Dr. Ergin told Bartlett that if she developed any adverse symptoms or abnormal reactions, she should stop taking the drug and contact his office.

Bartlett took the prescription to a nearby pharmacy, which filled it with Sulindac, a generic

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[4] For a more detailed summary of the case's factual and procedural background, see this court's recent summary judgment ruling. Bartlett v. Mut. Pharm. Co., 2010 DNH 112, 3-8.

version of the drug, manufactured by Mutual. The pharmacy gave Bartlett a "prescription advisor," which she read, that advised her to "check with your doctor" if certain possible side effects, including diarrhea, "continue or are bothersome," to "check with your doctor as soon as possible if you experience rash or other skin conditions," and to "contact your doctor immediately if you experience swelling of hands, face, lips, eyes, throat, or tongue" or certain other symptoms.

Within weeks of the prescription, Bartlett began to feel sick. Her symptoms started on a Saturday as a bout with diarrhea, which continued into Sunday. She then went to work on Monday, but did not feel well enough to work a full day. That was the first day she contacted Dr. Ergin or her primary care physician. She went to an emergency room the following day (Tuesday), at which point she was complaining of a skin rash, fever, and eye irritation. She continued taking Sulindac until that point (and possibly a little longer, since there is a discrepancy between the number of pills she recalls taking and the number of pills left, see Bartlett, 2010 DNH 112, at 37-38). Soon thereafter, she was diagnosed with SJS/TEN. She spent about three months in the hospital recovering, two of them in a medically induced coma, and emerged with permanent injuries.

III. Analysis

A. *Defenses based on Bartlett's conduct*

Mutual has asserted four affirmative defenses based on Bartlett's failure to stop taking the drug Sulindac and/or to seek medical care as soon as she began feeling sick. The first defense is comparative negligence. See N.H. Rev. Stat. § 507:7-d. The second is

plaintiff's misconduct, which is the strict liability equivalent of comparative negligence.[5] See Thibault v. Sears, Roebuck & Co., 118 N.H. 802, 813 (1978). The third is apportionment of liability. See N.H. Rev. Stat. § 507:7-e; DeBenedetto v. CLD Consulting Eng'rs, Inc., 153 N.H. 793, 804 (2006). The fourth is superseding or intervening cause. See Marcotte v. Timberlane/Hampstead Sch. Dist., 143 N.H. 331, 347-48 (1999).

All of those defenses have at least one element in common: causation. Mutual must prove by a preponderance of the evidence that Bartlett's conduct caused or contributed to her injuries. See N.H. Rev. Stat. § 507:7-d (comparative negligence--defendant has "burden of proof as to the existence or amount of fault attributable" to the plaintiff); Thibault, 118 N.H. at 813 (plaintiff's misconduct--defense not available "if plaintiff's misconduct did not cause the loss or injury"); Tiberghein v. B.R. Jones Roofing, Co., 156 N.H. 110, 115 (2007) (apportionment--defense involves "fault allocation . . between parties who have causally contributed to an accident"); Bruzga v. PMR Architects, P.C., 141 N.H. 756, 757-58 (1997) (superseding cause--defendant must show that superseding event "breaks the causal connection" between its conduct and plaintiff's injuries).

Although Mutual has not conceded the underlying premise that Sulindac caused Bartlett's SJS/TEN, see document no. 320, at 3 (noting that Mutual has no intent to challenge that point but will require Bartlett to prove it), its causation theory for these defenses seems to be that Bartlett's injuries would have been

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[5] Mutual sometimes refers to this defense as "failure to follow instructions."

less severe if she had stopped taking Sulindac and gone to the emergency room immediately after she started to feel sick with diarrhea, rather than waiting a few days until she had developed more serious symptoms. Mutual has not, however, designated any experts to testify in support of that theory. Instead, Mutual relies on the deposition testimony of various treating physicians (as well as one of Bartlett's experts), all of whom testified that immediate cessation of the offending drug is the first and most important aspect of treating a drug reaction.

None of those witnesses, however, explained how or to what extent (if any) Bartlett's conduct affected her actual injuries. To the contrary, some of the treating physicians suggested that medical knowledge of SJS/TEN has not advanced to the point where that question can be reliably answered. Dr. John Schulz, for example, testified that "the horse is out of the barn" after the initial "medication exposure" and that "once the syndrome is initiated, God knows where it will plateau." Similarly, Dr. Colleen Ryan acknowledged that while it "makes sense" to stop taking the drug immediately, "it's unclear the relationship of dose to the process." Mutual's counsel echoed those sentiments during oral argument on the summary judgment motions, representing to the court that a person could take only one Sulindac pill and "be struck to the same degree as Ms. Bartlett was in this case." Document no. 220, at 53.

The only witness who ventured an opinion on this causation theory is Mutual's expert Dr. Robert Stern, who testified at his deposition that "there is a possibility that since Sulindac may have been the cause of [Bartlett's] reaction, she may have had a

somewhat less severe outcome" if she had stopped taking the drug earlier. He then repeated: "That's a possibility." But Mutual needs to prove more than a mere possibility; it needs to prove a probability. Thus, Dr. Stern's conclusory opinion is not enough to sustain Mutual's defenses. The court also notes that Dr. Stern's opinion was expressed for the first time at his deposition, not in his expert report, and thus was not properly disclosed under Fed. R. Civ. P. 26 (a)(2)(B)(i).

Without expert testimony, the jury has no reliable way of determining whether, or to what extent, Bartlett's conduct caused or contributed to her injuries, which were far beyond the experience of average jurors. See Lemay v. Burtnett, 139 N.H. 633, 635 (1995) ("Expert testimony is required whenever the matter to be determined is so distinctly related to some science, profession, business or occupation as to be beyond the ken of the average layman."); Thorpe v. New Hampshire, 133 N.H. 299, 304 (1990) (explaining that expert testimony is necessary if "any inference of the requisite causal link must depend on observation and analysis outside the common experience of jurors"). Any finding of causation would be purely speculative on this record. See Lockridge v. Univ. of Me. Sys., 597 F.3d 464, 471 n.6 (1st Cir. 2010) ("unsupported speculation . . . is insufficient to forestall summary judgment").

Since Mutual has not presented sufficient evidence to establish a trialworthy defense of comparative fault, plaintiff's misconduct, apportionment, or superseding cause based on Bartlett's conduct, Bartlett is granted judgment as a matter of law on those defenses.

B. *Defenses based on Dr. Ergin's conduct*

Mutual has also asserted two defenses based on Dr. Ergin's conduct, including specifically his failure to read Sulindac's warning label before prescribing the drug and/or his failure to warn Bartlett that the drug could cause SJS/TEN. The first defense is third-party negligence and apportionment of liability. See N.H. Rev. Stat. § 507:7-e; DeBenedetto, 153 N.H. at 793. The other is superseding or intervening cause. See Marcotte, 143 N.H. at 347-48. This court will address each defense in turn.

i. Apportionment

Under New Hampshire law, "[w]here the defendant seeks to reduce or eliminate the plaintiff's recovery by apportioning professional liability" to a doctor who is not a party to the litigation, the defendant must "carry the plaintiff's burden of proof . . . N.H. Rev. Stat. § 507-E:2," which is the statute applicable to medical malpractice cases. Goudreault v. Kleeman, 158 N.H. 236, 256 (2009). That statute requires "affirmative evidence which must include expert testimony of a competent witness' of the standard of reasonable care, breach thereof and proximate causation of damages." Id. (quoting N.H. Rev. Stat. § 507-E:2) (emphasis added).

Mutual has not designated any expert witnesses to opine on those three elements. Instead, Mutual relies on deposition testimony by two of Bartlett's experts, Drs. Randall Tackett and Roger Salisbury. This court does not see how Mutual could elicit such testimony at trial consistent with the Federal Rules of Evidence and the Federal Rules of Civil Procedure. The testimony would be beyond the permissible scope of cross-examination (accepting Bartlett's representation at the

final pre-trial conference that she will not ask about such matters on direct examination). See Fed. R. Evid. 611(b). And to the extent that Mutual intends to call Drs. Tackett and Salisbury in its own case, it failed to make the timely expert disclosures required by Fed. R. Civ. P. 26 (a)(2)(A).

This court recognizes that, under some circumstances, "a trial court has discretion to decide whether to require a witness to testify for an opposing party" at trial, including an expert witness. Jasty v. Wright Med. Tech., Inc., 528 F.3d 28, 39 (1st Cir. 2008). But there is no requirement that the court do so, especially "[i]n the absence of any showing of a need for [the opposing party] to call the witness." Id. (affirming trial court's decision not to allow one party to call the other party's damages expert). This court is not inclined to exercise its discretion to allow such testimony here. Any "need" that Mutual may have to call Bartlett's witnesses is entirely of its own making, in that it failed to designate its own expert to testify about the standard of care (despite long ago disclosing an apportionment defense based on Dr. Ergin's conduct, see documents no. 11 and 322-1). Allowing Mutual to bypass the strictures of Rule 26 by simply posing out-of-scope questions to Bartlett's experts at their depositions would put Bartlett at an unfair disadvantage, since her expert proof on this issue was confined by Rule 26.

In any event, even if Mutual could use the testimony of Bartlett's experts, that testimony would still be insufficient to sustain Mutual's apportionment defense. One of Bartlett's experts, Dr. Tackett, is a pharmacologist, not a treating physician. Thus, he is not qualified to express an expert opinion on the

standard of care that Dr. Ergin, an orthopedic surgeon, should have followed in prescribing a drug like Sulindac. See Fed. R. Evid. 702. Moreover, even if he were qualified, Dr. Tackett did not testify that the standard of care required Dr. Ergin to read Sulindac's label or to warn Bartlett that the drug could cause SJS/TEN. At most, his testimony suggests that Dr. Ergin should have "provided [Bartlett] with a sufficient warning about if she had side effects to contact him." That is precisely the warning that Dr. Ergin gave, so Dr. Tackett's testimony is of no help to Mutual in proving these defenses.

Bartlett's other expert, Dr. Salisbury, is a burn surgeon who has some experience prescribing drugs that carry a risk of SJS/TEN, so he arguably is qualified to opine about the applicable standard of care. See id. But his testimony also fails to establish that Dr. Ergin breached the standard of care in a way that caused or contributed to Bartlett's injuries. See Goudreault, 158 N.H. at 256. Dr. Salisbury opined in his expert report that Sulindac's label should have included the following statement: "patients should be warned to discontinue NSAID should they develop any rash, fever without an alternative explanation, or mucosal symptoms." Again, however, Dr. Ergin did advise Bartlett to stop taking the medication and contact his office if she developed any adverse symptoms or abnormal reactions. And in any event, there is no expert testimony regarding how, or to what extent, earlier cessation of the drug would have changed Bartlett's injuries. See Part III.A, supra.

Dr. Salisbury also testified at his deposition that physicians "have the responsibility," as a matter of "generally accepted practice in medicine," to review the

warning label or Physician's Desk Reference entry (which also contains the warning) for drugs that they prescribe. He explained that the "reason for that" is "not only to help them in understanding the drug, but in order to counsel the patient what to look for and what problems may occur with stopping the drug." But Dr. Ergin already knew, even without reading Sulindac's warning label, that the drug could cause SJS/TEN, which is essentially all that the label said in that regard.[6] There is no evidence to suggest that his failure to read the label affected his decisionmaking process and thus no evidence to suggest that it caused or contributed to Bartlett's injuries.

This defense ultimately stands or falls on whether the standard of care required Dr. Ergin, knowing that Sulindac could cause SJS/TEN, to warn Bartlett specifically of that remote but serious risk and what it could entail. Dr. Salisbury expressed no opinion on that issue. His statement that the "reason" for reading the drug's label is to help the doctor "counsel the patient what to look for [i.e., early symptoms] and what problems may occur with stopping the drug [i.e., as opposed to taking it]" does not address which types of risks should be conveyed to the patient, whether Sulindac's risk of SJS/TEN falls in that category, or how that risk should have been conveyed.

This court has no doubt that Mutual's evidence of Dr. Ergin's negligence, if presented by a plaintiff in a medical malpractice case, would be considered insufficient as a matter of law. Under Goudreault, that

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[6] Dr. Salisbury's opinion that Dr. Ergin was "underinformed... about the known and scientifically knowable risks of Sulindac" was relative to what Sulindac's label should have said (in his view), not what the label actually said. It is thus irrelevant here.

means it is also insufficient as a matter of law to sustain Mutual's apportionment defense.

ii. Superseding cause

Mutual's superseding cause defense fares no better. In order to establish that defense, Mutual must prove that the superseding cause was not reasonably foreseeable. See, e.g., Marçotte, 143 N.H. at 348. Mutual has not even attempted to argue, nor could any reasonable jury find, that Dr. Ergin's failure to read the Sulindac label and/or his failure to warn Bartlett of the drug's risk of SJS/TEN were unforeseeable to Mutual. Indeed, as Mutual emphasized in arguing for summary judgment on Bartlett's failure-to-warn claims, and as this court noted in its order granting summary judgment to Mutual, there are many cases with very similar facts. See Bartlett, 2010 DNH 112, at 14 (citing examples).

Since Mutual has not presented sufficient evidence to establish a trialworthy defense of apportionment or superseding cause based on Dr. Ergin's conduct, Bartlett is granted judgment as a matter of law on those defenses as well.

IV. Conclusion

For the reasons set forth above, Bartlett is granted judgment as a matter of law on Mutual's affirmative defenses of comparative fault, apportionment, plaintiff's misconduct, and superseding cause.

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: August 12, 2010

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v. Civil No. 08-cv-00358-JL

Mutual Pharmaceutical Company, Inc.

MEMORANDUM ORDER

Plaintiff Karen Bartlett has moved for a jury instruction stating that she does not have to prove that Sulindac had an inadequate warning to prevail on her defective design claim, but that such evidence may be considered by the jury as a factor in determining whether Sulindac was unreasonably dangerous to consumers. She relies on the following passage from Vautour v. Body Masters Sports Industries, Inc., 147 N.H. 150 (2001):

> Under a risk-utility approach, a product is defective as designed if the magnitude of the danger outweighs the utility of the product.... In order to determine whether the risks outweigh the benefits of the product design, a jury must evaluate many possible factors including the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product's effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an

> unreasonable risk of harm from hidden dangers or from foreseeable uses.

Id. at 154 (emphasis added). Nearly identical language appears in a series of earlier New Hampshire Supreme Court cases. See Price v. BIC Corp., 142 N.H. 386, 390 (1997); LeBlanc v. Am. Honda Motor Co., 141 N.H. 579, 585 (1997); Chellman v. Saab-Scania AB, 138 N.H. 73, 77-78 (1993).

Mutual argues, in response, that Bartlett cannot present any evidence regarding Sulindac's warning, because this court recently granted summary judgment on Bartlett's failure-to-warn claims due to a lack of causation between the warning and her injuries. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112, at 11-22 (finding no causation because, among other things, Bartlett's doctor did not read or rely upon the drug's warning).[1] In light of that ruling, Mutual argues that Sulindac's warning is no longer relevant and that Bartlett, to prevail on her defective design claim, must prove that Sulindac was unreasonably dangerous regardless of what its warning said.

After reviewing the relevant case law, discussing this matter with the parties during a conference call on August 13, 2010, and reviewing their written

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[1] Mutual recently withdrew its "comment k" defense, which depended in part on the warning's adequacy. See Bartlett, 2010 DNH 112, at 24-25 (describing the requirements of that defense) (citing Restatement (Second) of Torts § 402A, cmt. k (1965)); document no. 332 (withdrawing the defense). Until that defense was withdrawn, there was no dispute that evidence of the warning's adequacy could be presented at trial, which is why this issue has not been resolved until now. *See* Bartlett v. Mut. Pharm. Co., 2010 DNH 131, 13 n.5 (reserving judgment on this issue); see also Bartlett v. Mut. Pharm. Co., 2010 DNH 123, 4 n.1 (same).

submissions,[2] this court concludes that the warning is still relevant to Bartlett's defective design claim, but not in the same way that it would be in the context of a failure-to-warn claim. For Bartlett to prevail on her defective design claim, she must prove that Sulindac was unreasonably dangerous despite its warning, not because of it. Evidence regarding the warning may be admitted for that purpose.

I. Legal framework

The New Hampshire Supreme Court has made clear that "design defect and failure to warn claims are separate" ways of establishing that a manufacturer is strictly liable for a defect in a product. See LeBlanc, 141 N.H. at 586. Our court of appeals, applying New Hampshire law, has said the same thing. See Cheshire Med. Ctr. v. W.R. Grace & Co., 49 F.3d 26, 32 (1st Cir. 1995) (stating that "manufacturing defect, design defect, and warning defect [are] three different ways of proving product defect, not just ... factors bearing upon one way of proving product defect"); see also Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 657 (1st Cir. 1981) (separately analyzing design defect and failure-to-warn claims involving a prescription drug). The standard jury instructions in New Hampshire also include a separate section for each type of strict liability claim; there is no mention of warnings in the design defect section. See Walter L. Murphy & Daniel C. Pope, New Hampshire Civil Jury Instructions §§ 23.2 and 23.4, at 23-3 and 23-5 (2007).

Nevertheless, as our court of appeals has observed, "New Hampshire case law supports the proposition that evidence concerning the existence and adequacy of

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[2] Documents no. 339, 341, 342, and 344.

a warning is relevant not only to a warning defect claim, but also to a design defect claim." Cheshire, 49 F.3d at 32 (citing Reid v. Spadone Mach. Co., 119 N.H. 457, 463 (1979)); see also Duford v. Sears, Roebuck & Co., 833 F.2d 407, 411-12 (1st Cir. 1987) ("The jury might have based liability solely on the inadequacy of the warnings .... Alternatively, or perhaps in conjunction with a belief that the warnings were only marginally sufficient, the jury might have found" the product unreasonably dangerous). Since that observation, three more New Hampshire Supreme Court cases have expressly stated that one of many factors the jury may consider in a defective design case is "the presence and efficacy of a warning to avoid an unreasonable risk of harm." Vautour, 147 N.H. at 154; see also Price, 142 N.H. at 390; LeBlanc, 141 N.H. at 585.

II. Analysis

The question here, which has not been answered in any of the previous cases, is whether a warning's adequacy is still relevant to a defective design claim where the court has granted summary judgment on the plaintiff's failure-to-warn claim due to a lack of causation between the warning and the plaintiff's injuries. See Bartlett, 2010 DNH 112, at 11-22. Mutual argues that if an inadequate warning is part of the reason why a product is deemed to be unreasonably dangerous, and the warning did not cause the plaintiff's injuries, then the design defect claim too must fail for lack of causation. Mutual's reasoning is that the warning would then constitute part of the product's defective condition, and it is black-letter law that the defective condition must cause the plaintiff's injuries. See Vautour, 147 N.H. at 154.

This court agrees with that reasoning, at least to some extent. Bartlett cannot be allowed to circumvent this court's summary judgment ruling by using Sulindac's warning to establish that the drug is unreasonably dangerous (i.e., arguing that Sulindac is unreasonably dangerous because of its warning), where this court has already ruled that any inadequacy in the warning did not cause Bartlett's injuries. That would effectively turn this case back into a failure-to-warn case, rendering the summary judgment ruling meaningless.

But that is not how the New Hampshire Supreme Court seems to have envisioned the warning's role in a design defect case. Instead, the cases suggest (on a close reading) that the jury, if it determines that the product would be unreasonably dangerous without any warning, may consider "the presence and efficacy of a warning to avoid an unreasonable risk of harm." Vautour, 147 N.H. at 154 (emphasis added); Price, 142 N.H. at 390; LeBlanc, 141 N.H. at 585; cf. also Bellotte v. Zayre Corp., 116 N.H. 52, 55 (1976) (distinguishing "the initial question of whether the product was unreasonably dangerous" from the question of the "adequacy of warning of a product unreasonably dangerous without warnings"). In other words, the plaintiff must prove that the product was unreasonably dangerous despite any warning in place at the time of its sale.

Under that approach, the inadequacy of the warning is not a part of the product's defective condition and thus need not be causally connected to the plaintiff's injuries. Indeed, the adequacy of the warning is not really the issue that the jury is being asked to decide. The issue is whether the warning,

adequate or not, avoids the product's otherwise unreasonable danger. The jury could conclude that a product is unreasonably dangerous even if its warning is adequate, or better than adequate. See, e.g., Duford, 833 F.2d at 411 ("a suitable warning is not necessarily a conclusive defense in a defective design case"); accord LeBlanc, 141 N.H. at 586.

Mutual argues that unless Bartlett can show that "no warning accompanying the product would have removed [its] unreasonable danger," then her defective design claim effectively turns on the strength of Sulindac's warning, making it a failure-to-warn claim for which Bartlett cannot prove causation. But that argument is problematic for at least two reasons.

First, it would mean that, because Bartlett's doctor did not read Sulindac's warning, Mutual would not only be shielded from liability for having an inadequate label (i.e., failure-to-warn), but also would get credit for having the best possible warning for purposes of the defective design analysis, even though this court has ruled that the warning's adequacy is a matter of genuine dispute on the current record. See Bartlett, 2010 DNH 112, at 8-11. Indeed, under Mutual's reasoning, it would get credit for having the best possible warning even if its warning were gibberish.

Second, it assumes that a warning, even a legally adequate one, which fails to avoid a product's unreasonable danger automatically becomes the product's defect (and hence must be causally connected to the plaintiff's injuries) if the jury can imagine "any warning [that] would have removed the unreasonably dangerous nature of the product." Assume, for example, that the jury found that Sulindac had a legally adequate warning, but that the product was

still unreasonably dangerous. Under Mutual's reasoning, if the jury could imagine some hypothetical "superwarning" that would have avoided the unreasonable danger (e.g., sending a personal messenger to every doctor's home and office in America), the legally adequate warning would thereby become the product's defect. This court cannot accept either of those propositions.

Mutual alternatively suggests that the jury could be instructed to determine whether Sulindac was unreasonably dangerous "without regard to the warning." But that strikes the court as an empty and artificial instruction. To the extent that a warning affects a product's level of dangerousness and/or utility, it is impossible to analyze whether a product is unreasonably dangerous "without regard to the warning," unless that means analyzing the product "as if there were no warning." Mutual is unwilling to accept that sort of instruction as a means of keeping the warning out of the case (even if that were permissible, which is an issue on which this court expresses no opinion).

For all of these reasons, this court concludes that the best course, and the one most faithful to New Hampshire precedent, is to give a jury instruction that tracks the language of the New Hampshire Supreme Court cases (i.e., that the jury, if it determines Sulindac would be unreasonably dangerous without any warning, may consider "the presence and efficacy of a warning to avoid an unreasonable risk of harm") and to allow evidence and argument about Sulindac's warning, provided it is properly directed at whether the warning in place at the time of Bartlett's

prescription avoided an otherwise unreasonable danger (and not whether it created unreasonable danger).[3]

Bartlett's motion for a jury instruction[4] is therefore DENIED, without prejudice to any objections or counter-proposals that either party may make in response to this court's proposed jury instructions.

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: August 15, 2010

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[3] Bartlett argues that "if the evidence of Sulindac's inadequate label is relevant ... such relevance makes all the relevant evidence admissible, not a small portion" of it. If she means, by that tautology, that any evidence relevant to her former failure-to-warn claim is automatically relevant to her defective design claim, then she is incorrect. Much of that evidence (especially the evidence relating to causation) is no longer relevant. Indeed, Bartlett seemed to acknowledge that point in withdrawing her prescribing doctor Tahsin Ergin as a witness, saying that she is "unaware of any relevant testimony he may give" now that the failure-to-warn claims and Mutual's third-party apportionment defense are no longer part of the case. Document no. 334.

To give another example not tied to Dr. Ergin, whether Mutual hypothetically could or should have filed a citizen's petition with the FDA regarding Sulindac, and how the FDA hypothetically would have responded to such a petition, have no relevance to whether Sulindac's warning in place at the time of Bartlett's prescription avoided an otherwise unreasonable danger, or to any other issue remaining in the case. Conversely, the fact that FDA actually required changes to all NSAID labels shortly after Bartlett's injuries, and the fact that it instituted a "black box" warning for Bextra, are relevant to that issue.

[4] Document no. 339.

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Mutual Pharmaceutical Company, Inc.

Civil No. 08-cv-00358-JL
Opinion No. 2010 DNH 164

MEMORANDUM ORDER

This products liability case arises out of severe injuries that plaintiff Karen Bartlett suffered after ingesting sulindac, a prescription drug manufactured by the defendant, Mutual Pharmaceutical Company. Bartlett brought claims against Mutual for strict liability, negligence, and fraud under New Hampshire common law. Her principal theories were that sulindac is a defective product unreasonably dangerous to consumers and that Mutual failed to warn of the drug's safety risks. This court, which has jurisdiction under 28 U.S.C. § 1332(a)(1) (diversity), granted summary judgment to Mutual on Bartlett's strict liability and negligence claims to the extent they were based on failure to warn, and also on her fraud claim, because she could not prove that sulindac's allegedly inadequate warning caused her injuries. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112. Bartlett proceeded to trial and prevailed on her strict liability claim of defective design.

After the summary judgment ruling, but in advance of trial, this court ordered the parties to brief whether Bartlett had sufficient evidence to support her

negligence claim (under some theory other than failure to warn) and, if not, whether she could still pursue enhanced compensatory damages in connection with her strict liability claim. Bartlett responded by submitting her evidence in support of three negligence theories: that Mutual failed to (1) seek Food & Drug Administration ("FDA") approval of a patient medication guide for sulindac; (2) survey the medical literature for information about sulindac's safety risks and report such information to the FDA; and (3) file a citizen's petition with the FDA regarding sulindac's safety risks. She further argued that, even if this court rejected those negligence theories, the jury could award enhanced compensatory damages on her strict liability claim.

Having reviewed Bartlett's submission and Mutual's corresponding brief, this court concludes that Bartlett's negligence claim is mostly a self-described attempt to "resurrect" her failure-to-warn theories, in contravention of this court's summary judgment ruling. See Bartlett, 2010 DNH 112, at 11-22. To the extent that the negligence claim is based on conduct other than Mutual's alleged failure to warn, Bartlett has not presented sufficient evidence to prove that conduct caused her injuries. And since her claim for enhanced compensatory damages is based on that same conduct, it also fails for lack of causation, regardless of whether a strict liability claim can theoretically sustain such damages. Mutual is therefore granted judgment as a matter of law on Bartlett's claims for negligence and enhanced compensatory damages. See Fed. R. Civ. P 56.

The court initially announced this ruling in a summary order issued before trial. See document no.

329. This order sets forth the court's reasoning in greater detail.

I. Applicable legal standard

"It is without question that district courts, in appropriate circumstances, are entitled to enter summary judgment suasponte." P.R. Elec. Power Auth. v. Action Refund, 515 F.3d 57, 64 (1st Cir. 2008). To guard against any unfairness to the parties, our court of appeals has "required two conditions prior to the district court's exercise of such a right:" (1) "the discovery process must be sufficiently advanced that the parties have enjoyed a reasonable opportunity to glean the material facts," and (2) "the district court must provide the targeted party appropriate notice and a chance to present its evidence on the essential elements of the claim." Id. at 64-65. Both of those conditions have been met here: the discovery process is over, and this court gave Bartlett notice and an opportunity to present evidence on her claims for negligence and enhanced compensatory damages.[1] This court will therefore evaluate those claims as it would in the context of a summary judgment motion filed by Mutual.

Summary judgment is appropriate where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P 56(c)(2). An issue is "genuine" if it could reasonably

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[1] See documents no. 281 (order), 305 to 318 (Bartlett's brief and supporting exhibits), and 303 (Mutual's brief). In addition to the briefing, this court discussed its concerns about Bartlett's negligence claim with the parties during the final pre-trial conference. See document no. 301.

be resolved in either party's favor at trial, and "material" if it could sway the outcome under applicable law. Mulvihill v. Top-Flite Golf Co., 335 F.3d 15, 19 (1st Cir. 2003). In making that determination, the "court must scrutinize the record in the light most flattering to the party opposing the motion, indulging all reasonable inferences in that party's favor." Id. The following factual summary is consistent with that approach.

II. Background

In December 2004, Bartlett sought medical treatment for pain in her right shoulder. Her doctor, Tahsin Ergin, prescribed a non-steroidal anti-inflammatory drug ("NSAID") called Clinoril, which the FDA has approved as a treatment for acute shoulder pain. Dr. Ergin did not read the potential adverse reactions and safety warnings listed in the drug's label (or "package insert"), but he knew from his medical background that sulindac and other NSAIDs carried some risk of causing potentially fatal skin conditions called Stevens-Johnson Syndrome ("SJS") and toxic epidermal necrolysis ("TEN"). See Dorland's Illustrated Medical Dictionary 1872 (31st ed. 2007). It was not his usual practice to discuss that risk with patients, and he did not do so with Bartlett.

Bartlett took the prescription to a pharmacy in Plaistow, New Hampshire, which filled it with sulindac, a generic version of the drug, manufactured by Mutual. The pharmacy gave Bartlett a "prescription advisor," which she read, that advised her to "check with your doctor as soon as possible if you experience rash or other skin conditions." Within weeks, Bartlett went to a local emergency room complaining of skin blisters, a fever, eye irritation, and

other symptoms. She was soon diagnosed with a severe case of SJS/TEN. The consensus among her doctors was that her SJS/TEN was a side effect of sulindac. She spent about three months in the hospital recovering, two of them in a medically induced coma, and emerged with permanent injuries, including blindness.

More than a year before Bartlett's prescription, an international medical journal published a study of the link between NSAIDs and SJS/TEN. See Maja Mockenhaupt et al., The Risk of SJS and TEN Associated with NSAIDs: A Multinational Perspective, 30 Journal of Rheumatology 2234-2240 (Oct. 2003). The article revealed that, from 1980 to 1997, the FDA's adverse event reporting system received 89 reports of SJS/TEN attributed to sulindac, more than the number of reports for any other NSAID on the market and all but four drugs of any kind. The article also noted that sulindac was one of four NSAIDs whose rate of reported SJS/TEN cases, per one million prescriptions, was not significantly lower than that of piroxicam, which the authors chose as the "comparator drug" because of its "high risk" in a controlled study.[2]

Mutual was not aware of that Journal of Rheumatology article or adverse event reporting data, because (by its own admission) it had not been monitoring the medical literature for information about sulindac's safety risks. See document no. 149, at

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[2] Unpublished drafts of the article, prepared privately for the drug manufacturer Pharmacia by Dr. Robert Stern (who was later retained as an expert witness by Mutual) in 2001 and 2002, listed the precise reporting rates of SJS/TEN for various NSAIDs. Sulindac's rate was higher than that of any other NSAID listed. See documents no. 307-1 and 308-1.

15. Mutual believed that the manufacturer of Clinoril, the brand-name version of the drug, was responsible for such monitoring and for reporting pertinent safety information to the FDA. Id. at 16, 22-23; but see Bartlett, 2010 DNH 112, at 30-32 (concluding that generic drug manufacturers are also responsible for safety surveillance and reporting under 21 C.F.R. § 314.80(b)).

While Bartlett was in the hospital battling SJS/TEN, a group of doctors (including two whom Bartlett later retained as expert witnesses) filed a citizen's petition with the FDA advocating a stronger SJS/TEN warning in the label for another NSAID, ibuprofen. Soon thereafter, the FDA required not just ibuprofen, but all NSAIDs, including sulindac, to insert a stronger SJS/TEN warning in their labels. See Bartlett, 2010 DNH 112, at 15 n.6 (setting forth the language of that new warning). The FDA also required that all NSAIDs be accompanied by a patient medication guide, see 21 C.F.R. § 208.1, with an express warning of "life- threatening skin reactions" and an instruction that patients should stop taking the drug if they experienced "skin rash or blisters with fever."

In a written response to the citizen's petition, the FDA explained that it had "engaged in a comprehensive review of the risks and benefits, including the risks of SJS/TEN, of all approved NSAID products," and that it had specifically reviewed the Journal of Rheumatology article and the adverse event reporting data referenced above. Based on that review, the FDA concluded that one NSAID, Bextra, should be withdrawn from the market due to its SJS/TEN and cardiovascular ("CV") risks. The FDA explained:

> We have concluded ... that Bextra has been demonstrated to be associated with an increased risk of serious adverse CV events. ... The increased risk of serious adverse CV events alone, however, would not be sufficient to warrant withdrawal of Bextra since we have no data showing that Bextra is worse than other NSAIDs with regard to CV risk. Our recommendation for withdrawal is based on the fact that, in addition to this CV risk, [Bextra] already carries a boxed warning in the package insert for serious, and potentially life-threatening, skin reactions (e.g., TEN, SJS, erythema multiforme) and FDA has received 7 spontaneous reports of deaths from these reactions. The reporting rate for these serious skin reactions appears to be greater for Bextra than other [NSAIDs called] COX-2 selective agents. ... To date, there have been no studies that demonstrate an advantage of [Bextra] over other NSAIDs that might offset the concern about these serious skin risks.

Bextra was the fourth drug to be removed from the market due, in part, to its SJS/TEN risk as demonstrated by adverse event reports.[3]

Although sulindac had more reported cases of SJS/TEN than any other NSAID and more reported deaths (39) than Bextra, the FDA did not recommend that sulindac be removed from the market after its "comprehensive review" of all NSAIDs in 2005. In fact, sulindac remains on the market to this day. Mutual

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[3] The others were benaxaprofen, zomepirac acid, and isoxicam. Since then, the FDA has also refused to approve the drug Provigil for pediatric use because of its SJS/TEN risk.

has never filed a citizen's petition with the FDA regarding the safety of sulindac or seeking its removal from the market. The company has, however, filed nine citizen's petitions for other reasons between 2001 and 2009, including one petition regarding the dosage form of sulindac and various petitions regarding safety information in the labels of other drugs (some manufactured by Mutual's competitors). The FDA has generally responded to those petitions in less than a year.

III. Analysis

As explained above, this court ordered the parties before trial to brief (A) whether Bartlett had sufficient evidence to support her negligence claim, and (B) if not, whether she could still pursue enhanced compensatory damages in connection with her strict liability claim. As explained below, the answer to both questions is no. Mutual is therefore granted judgment as a matter of law on Bartlett's claims for negligence and enhanced compensatory damages.

A. Negligence claim

Bartlett has submitted evidence in support of three negligence theories: that Mutual (1) failed to seek FDA approval of a medication guide for sulindac; (2) failed to survey the medical literature for information about sulindac's safety risks and to report such information to the FDA; and (3) failed to file a citizen's petition with the FDA seeking either sulindac's removal from the market or the removal of its approved indication for acute shoulder pain. Bartlett claims that "the duty that was breached [by Mutual] in

each of these areas is the failure to communicate with the FDA as a reasonable manufacturer would have."[4]

To prevail on any of those theories, Bartlett must prove that Mutual's negligent conduct caused her injuries. See Carignan v. N.H. Int'l Speedway, Inc., 151 N.H. 409, 414 (2004). Causation has two components: the plaintiff must show, first, "that the injury would not have occurred but for the negligent conduct," and second, "that the negligent conduct was a substantial factor in bringing about the harm." Id. Here, Bartlett claims that if Mutual had taken any of steps listed above, the FDA would have (1) required a patient medication guide for sulindac before her prescription, rather than after it, (2) removed sulindac's approved indication for acute shoulder pain, and/or (3) removed sulindac from the market, any of which would have prevented her from taking the drug and thus prevented her injuries.

This court will address each of Bartlett's negligence theories in turn. As explained below, most of them are really failure-to-warn theories and are therefore barred by this court's summary judgment ruling, which granted summary judgment to Mutual on all such theories. See Bartlett, 2010 DNH 112, at 11-22. The only one that is not a failure-to-warn theory is Bartlett's claim that the FDA would have removed Sulindac from the market if Mutual had advocated that removal in a citizen's petition or had submitted the latest safety information from the medical literature. But that claim fails because its causal

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[4] Bartlett expressly withdrew her claim for negligent design, see document no. 301, at 15, and implicitly withdrew or waived any other negligence theories by not raising them in her submission, see document no. 305.

chain depends on improbable inferences and speculation. See Enica v. Princip, 544 F.3d 328, 336 (1st Cir. 2008) ("summary judgment cannot be defeated by relying on improbable inferences, conclusory allegations, or rank speculation").

i. Patient medication guide

Bartlett's first negligence theory is that Mutual should have sought FDA approval of a patient medication guide for sulindac. The FDA may require that a drug be accompanied by a medication guide if it determines that "patient labeling could help prevent serious adverse effects," that safety information "could affect patients' decision to use, or to continue to use" the drug in the face of "serious risk(s)," or that "patient adherence to directions for use is crucial to the drug's effectiveness." 21 C.F.R. § 208.1. As discussed above, the FDA required a medication guide for sulindac and all other NSAIDs not long after Bartlett's prescription. Bartlett argues that the FDA would have required a medication guide before her prescription if Mutual had sought it, and that she never would have ingested sulindac if she had read the guide.

This court expressly rejected Bartlett's medication guide theory (among other failure-to-warn theories) in its summary judgment ruling, both because Bartlett failed to raise it in her summary judgment objection and because, on the merits,

> it is well established [under New Hampshire law] that a manufacturer's duty to warn of a drug's safety risks "requires that the physician, not the patient, be warned." Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 661 (1st Cir. 1981); see also Nelson v. Dalkon Shield Claimants Trust, No. 84-276-SD, 1994

> WL 255392, at *4 (D.N.H. June 8, 1994). Since Mutual had no duty to warn Bartlett directly, its failure to issue such a warning (in the form of a medication guide or otherwise) cannot serve as the basis for a finding of causation.

Bartlett, 2010 DNH 112, at 20. The principle articulated in that passage is known as the "learned intermediary" rule, because its underlying rationale "is that the prescribing physician, as the 'learned intermediary' standing between the manufacturer and the consumer/patient, is generally in the best position to evaluate the [drug's] potential risks and benefits ... and to advise the patient accordingly." Nelson, 1994 WL 255392, at *4 (quoting Garside v. Osco Drug, Inc., 976 F.2d 77, 80 (1st Cir. 1992)).

Bartlett's self-described attempt to "resurrect" her medication guide theory in the face of that express summary judgment ruling is really a motion for reconsideration. See Rodriguez-Antuna v. Chase Manhattan Bank Corp., 871 F.2d 1, 2 (1st Cir. 1989) ("a motion which asks the court to modify its earlier disposition ... solely because of an ostensibly erroneous legal result" is a motion for reconsideration). This court will analyze it as such. A motion for reconsideration must "demonstrate that the order was based on a manifest error of fact or law" and must be filed within 14 days of the order, unless the party shows cause for not filing it within that time. L.R. 7.2(e). Here, Bartlett sought reconsideration about a month after the court's ruling, well after the 14-day

deadline.[5] She has not shown good cause for that delay. Her request is therefore denied as untimely.

Even if it were timely, however, Bartlett's request for reconsideration would still be denied, because she has not identified a "manifest error of fact or law" in this court's ruling. She makes three arguments in that regard:

First, Bartlett argues that this court should not have considered her medication guide theory at all because it was "not raised" by Mutual's summary judgment motion, which in her view "missed the boat" by focusing solely on the drug's label. But this argument sinks. Mutual moved for summary judgment on all of Bartlett's claims, including her negligence claim, arguing that "failure to warn is the common thread in each alleged liability theory." Thus, Bartlett had the burden to come forward with evidence to support all of her failure-to-warn claims, including her medication guide theory and any other "non-label" theories. See Evans Cabinet Corp. v. Kitchen Int'l, Inc., 593 F.3d 135, 140 (1st Cir. 2010). Instead, she focused on her label-based theories. A motion for reconsideration "does not provide a vehicle for a party to undo its own procedural failures." Iverson v. City of Boston, 452 F.3d 94, 104 (1st Cir. 2006).[6]

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[5] By that point, Mutual had filed not only a motion for reconsideration of the summary judgment ruling, see document no. 263, but a motion for reconsideration of the court's denial of its first motion for reconsideration, see document no. 293.

[6] During oral argument on the summary judgment motion, this court asked Bartlett about her "non-label" theories in an abundance of caution, i.e., to determine if they might somehow salvage her failure-to-warn claims, not (as Bartlett seems to believe) in an attempt to expand its summary judgment ruling

Second, Bartlett argues that this court should create a special exception to the learned intermediary rule for medication guides, since they are a "new development" in the law, see 21 C.F.R. § 208.1, having been introduced by the FDA in 1998, four years after the most recent case that applied the learned intermediary rule under New Hampshire law. See Nelson, 1994 WL 255392, at *4. In her summary judgment objection, though, Bartlett called it "an uncontested claim [that] the learned intermediary doctrine means the drug company need only adequately warn the physician." She did not argue for a special exception for medication guides. A motion for reconsideration "does not ... allow a party to advance arguments that could and should have been presented" earlier. Iverson, 452 F.3d at 104.

Moreover, even if Bartlett's argument had been properly presented, this court is not persuaded that medication guides constitute so significant a change to prescription drug labeling as to warrant what would amount to a significant change to (and expansion of) state tort law. Indeed, the FDA expressed precisely the opposite view when it promulgated the medication guide regulation, stating that "FDA does not believe that this rule would adversely affect civil tort liability" because it "does not alter the duty, or set the standard of care for manufacturers," and because "courts have not recognized an exception to the 'learned intermediary' defense in [other] situations where FDA has required patient labeling." 63 Fed. Reg. 66378, 66383-66384 (Dec. 1, 1998).

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beyond the scope of Mutual's motion. Those theories would be barred now even if this court had never mentioned them.

Bartlett has not identified, nor has this court found, any case that supports her view that medication guides warrant a special exception to the learned intermediary rule, which remains "nearly universal." 5 Louis R. Frumer & Melvin I. Friedman, Products Liability § 50.04[2], at 50-58.1 (2010). "A federal court sitting in diversity cannot be expected to create new doctrines expanding state law," Noonan v. Staples, Inc., 556 F.3d 20, 27-28 (1st Cir. 2009), and this court declines Bartlett's invitation to do so here.

Third, Bartlett argues that a medication guide, because it is "reprinted at the end of the [drug's] labeling" or package insert, 21 C.F.R. 201.57(f)(2), can be considered a warning to doctors (not just patients) and thus is not barred by the learned intermediary rule. As explained in this court's summary judgment ruling, however, Bartlett's doctor did not read or rely upon sulindac's label before prescribing the drug to her. So the medication guide, even if reprinted there, would not have affected the doctor's decision or prevented Bartlett's injuries. Thus, Mutual's failure to seek a medication guide cannot be considered the cause of Bartlett's injuries. See Carignan, 151 N.H. at 414.[7]

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[7] While on the topic of medication guides, it is worth taking a moment to explain the evidentiary rulings on that topic. This court initially granted Mutual's motion in limine seeking to exclude from trial any evidence regarding medication guides, "because they would imply a duty to warn the patient, would be confusing to the jury and unfairly prejudicial to Mutual." Bartlett v. Mut. Pharm. Co., 2010 DNH 131, at 19 (citing Fed. R. Evid. 403). At trial, however, this court orally modified that ruling, allowing evidence of the medication guide to be admitted with a cautionary instruction designed to avoid juror confusion and unfair prejudice. The cautionary instruction was given several times during the trial, including in the final jury charge. See document no. 378, at 21-22. The reasons for that modification

ii. Removal of indication for shoulder pain

Bartlett's second negligence theory is that, if Mutual had filed a citizen's petition with the FDA or otherwise submitted information from the medical literature regarding sulindac's risk of SJS/TEN, the FDA would have removed sulindac's approved indication for acute shoulder pain, "advising doctors of this through effective means" and thereby preventing Bartlett's doctor from prescribing the drug to her for that purpose. As Bartlett's reference to "advising doctors" betrays, however, this too is really a failure-to-warn theory, which Bartlett could have and should have raised in her summary judgment objection. Since she failed to do so, the theory has been waived. See Iverson, 452 F.3d at 104 (a motion for reconsideration "does not ... allow a party to advance arguments that could and should have been presented" earlier).

Moreover, even if Bartlett's removal-of-indication theory had been properly presented, this court would have rejected it on the merits. A prescription drug's approved indications, like its potential adverse reactions and warnings, are set forth in its label. See

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were twofold. First, since the jury was allowed to consider the changes that the FDA made to sulindac's labeling in 2005, see Bartlett, 2010 DNH 131, at 4-7, and the medication guide was part of those changes, it was necessary to give the jury a complete and accurate understanding of what the FDA did. Second, this court determined that the jury could consider the medication guide in evaluating "the presence and efficacy of a warning to avoid an unreasonable risk of harm," which is an analytically distinct question from whether Mutual had a duty to warn via a medication guide. Bartlett v. Mut. Pharm. Co., No. 08-cv-358, 2010 WL 3303864, at *1 (D.N.H. Aug. 16, 2010) (document no. 345) (quoting Vautour v. Body Masters Sports Indus., Inc., 147 N.H. 150, 154 (2001)).

21 C.F.R. § 201.57(c). As explained in this court's summary judgment ruling, Bartlett's doctor did not read or rely upon sulindac's label before prescribing the drug to her. So the deletion from that label of the indication for acute shoulder pain would not have affected the doctor's decision or prevented Bartlett's injuries. Thus, Mutual's failure to seek a removal of the indication cannot be considered the cause of Bartlett's injuries. See Carignan, 151 N.H. at 414.

Seemingly unfazed by the rules of summary judgment, Bartlett also argues that her doctor might have learned of the removal-of-indication (or other label changes) from an FDA press release, public health advisory, or mass mailing to physicians. This court expressly rejected that argument in its summary judgment order, explaining that it had been "untimely and improperly raised" in Bartlett's separate limine briefing, not in her summary judgment objection (or even at oral argument on the summary judgment motion), and was therefore waived. See Bartlett, 2010 DNH 112, at 19 n.9. The argument has not become any more timely or proper in the intervening period.[8]

iii. Removal from the market

Bartlett's third negligence theory is that if Mutual had filed a citizen's petition with the FDA or otherwise submitted information from the medical literature regarding sulindac's risk of SJS/TEN (including the Journal of Rheumatology article, which revealed that sulindac had more reported cases of SJS/TEN in the

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[8] Moreover, Bartlett still has not presented any evidence that her doctor would have read any such materials—only his deposition testimony (unmentioned in her summary judgment and limine briefing) that "as physicians we'll often receive them." Of course, receiving a mass mailing is not the same as reading it.

FDA's adverse event database than any other NSAID), the FDA would have removed sulindac from the market entirely, thus preventing Bartlett's doctor from prescribing it and thereby preventing her injuries. This is Bartlett's only negligence theory that is not based on failure to warn and hence is not barred by this court's summary judgment ruling. Nevertheless, the theory suffers from a number of other fatal flaws.

The theory's most obvious flaw, which this court discussed briefly in a previous order, is that it is "contrary to what has actually happened." Bartlett, 2010 DNH 131, at 11. The FDA said that it "engaged in a comprehensive review of the risk and benefits, including the risks of SJS/TEN, of all approved NSAID products" in 2005, after receiving a citizen's petition from a group of doctors (two of whom later became Bartlett's experts). As part of that review, the FDA specifically considered the Journal of Rheumatology article and the adverse event reporting data. While deciding to strengthen the SJS/TEN warning on all NSAID labels, the FDA concluded that only one NSAID should be removed from the market due in part to its SJS/TEN risk: Bextra. "Sulindac remains on the market today ... even though the FDA has long been aware of the adverse event data and medical literature upon which Bartlett relies." Id. at 11-12.

Bartlett argues that sulindac's risk-benefit profile was actually even worse than Bextra's. Regardless of how the two drugs compare, however, the bottom line is that the FDA concluded that Bextra should be removed from the market, but that sulindac could stay on the market with a stronger SJS/TEN warning. Bartlett's theory that the FDA would have removed sulindac from the market if Mutual had submitted the

Journal of Rheumatology article and other available information from the medical literature is counterfactual. Cf. Buckman Co. v. Pls.' Legal Comm., 531 U.S. 341, 353 (2001) (Stevens, J., concurring in the judgment, joined by Thomas, J.) ("The fact that the FDA has done nothing to remove the devices from the market, even though it is aware of the basis for the [plaintiff's] fraud allegations, convinces me that [causation] cannot be proved.").

Bartlett attempts to overcome this problem by pointing to earlier, unpublished drafts of the Journal of Rheumatology article (prepared by defense expert Dr. Stern for the drug manufacturer Pharmacia in 2001 and 2002), which contain additional information about sulindac's SJS/TEN risk that did not appear in the final article. Specifically, the drafts reveal that sulindac's rate of reported SJS/TEN cases per million prescriptions (not just its absolute number of reports) was the highest of any NSAID listed. Bartlett argues that Mutual should have obtained those unpublished drafts and submitted them to the FDA, which (she claims) has never considered that reporting rate data and would have responded by recommending sulindac's removal from the market.

There is insufficient evidence, though, to support any of the links in that causal chain. Even assuming, dubitante, that a reasonable manufacturer would have asked the authors of a published, peer-reviewed article for their unpublished drafts (a proposition for which Bartlett has not offered any expert testimony or other evidence), there is no evidence from which a jury could reasonably conclude that such a request would have been granted. Dr. Stern testified that, because of his contract with Pharmacia, he had to seek Pharmacia's

permission even to use the unpublished data in developing the Journal of Rheumatology article. Pharmacia granted his request, but the current record provides no basis for reliably evaluating whether it would have allowed the unpublished drafts to be shared directly with a competitor like Mutual, leaving this link in the causal chain to speculation.

There is likewise no evidence from which a jury could reasonably conclude that Pharmacia did not itself share those unpublished drafts with the FDA. While Dr. Stern did not send the drafts to the FDA himself and has no "direct knowledge" of whether Pharmacia did so, he considers it a "high likelihood that Pharmacia would have filed a report of this type" with the FDA. Of course, Dr. Stern's speculation is not dispositive. But without any evidence of what Pharmacia actually did, it would be equally speculative to conclude that the FDA never received the drafts. See Enica, 544 F.3d at 336 ("summary judgment cannot be defeated by relying on improbable inferences, conclusory allegations, or rank speculation").

Moreover, even if Pharmacia never shared Dr. Stern's reporting rate calculations with the FDA, those calculations were based entirely on publicly available information from the federal government. Dr. Stern used, as his numerator, the number of SJS/TEN reports for each drug in the FDA's own adverse event reporting database. And he used, as his denominator, the estimated number of prescriptions for each drug in the National Ambulatory Medical Care Survey ("NAMCS"), compiled by the federal Centers for Disease Control and Prevention ("CDC"). The FDA's analyses of Bextra in 2005 and Provigil in 2007 both

indicate that, either through those government sources or other means, the FDA has the ability to calculate and has calculated the SJS/TEN reporting rates for NSAIDs.[9]

Finally, even assuming, dubitante, that the FDA was unaware of the precise SJS/TEN reporting rates for sulindac and other NSAIDs, the final article published in the Journal of Rheumatology (which the FDA definitely did review) expressly listed sulindac as one of only four NSAIDs with a reporting rate comparable to that of piroxicam, which the authors chose as the "comparator drug" because of its "high risk" in a controlled study. The clear implication was that sulindac had one of the highest SJS/TEN reporting rates among NSAIDs (albeit without reference to the precise numbers). Despite that information, the FDA did not conclude that sulindac should be removed from the market. Bartlett's claim that more specific data would have changed the FDA's mind is, again, pure speculation. See Enica, 544 F.3d at 336.

This court recognizes that it is not possible to prove with absolute certainty what the FDA would have done in response to hypothetical communications that never occurred. To the extent, if any, that failure to communicate with the FDA can serve as a basis for a

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[9] See document no. 309-1, at 12 ("While other COX-2 selective and non-selective NSAIDs also have a risk for these rare, serious skin reactions, the reported rate for these serious side effects appears to be greater for Bextra than for other COX-2 agents."); id. at 17 ("The reporting rate for these serious skin reactions appears to be greater for Bextra than other COX-2 selective agents."); document no. 309-3, at 19 ("the calculated reporting rate for [Provigil] associated SJS/TEN in all ages in the U.S. is 5.7 per 1,000,000 patients as compared to the background rate of 1-2").

state negligence claim, see infra (discussing federal pre-emption concerns raised by such claims under Buckman, 531 U.S. at 341), the plaintiff must be given some inferential leeway in establishing causation. See, e.g., Stanton v. Astra Pharm. Prods., Inc., 718 F.2d 553, 568 (3d Cir. 1983) (holding, albeit before Buckman, that a reasonable jury could find causation based on "evidence tending to show that the information withheld from the FDA was of great importance ... and that the FDA would have taken action had it been aware of [the drug's] propensity to cause adverse reactions"). But the inferences still must be reasonable, not improbable or based "upon speculation as to the FDA's behavior in a counterfactual situation," which is the case with Bartlett's negligence theory. Buckman, 531 U.S. at 354 (Stevens, J., concurring in the judgment).

Bartlett also seems to be suggesting the FDA would have taken a harder look at sulindac and ultimately reached a different decision if Mutual, one of the drug's own manufacturers, had filed a citizen's petition requesting its removal from the market. But that too is speculative, at least on the record before the court. There is no evidence to suggest that the FDA makes its decisions that way. The FDA claimed to have conducted a "comprehensive review" of all NSAIDs, including sulindac, and their SJS/TEN risk in 2005, after receiving a citizen's petition from Bartlett's experts. Whether or not that review was truly comprehensive, it is pure speculation to assume that the FDA would have conducted a more thorough review in response to a citizen's petition from Mutual.

Moreover, Bartlett's argument that Mutual should have filed a citizen's petition with the FDA highlights

yet another flaw with her negligence theory, which is that Mutual did not even need the FDA's permission to stop selling sulindac. It could have done so unilaterally at any time. The reason that Bartlett has inserted the FDA as a middleman is that "almost all of the opinions which have addressed the issue have found that there is no common law duty to recall" products from the market, even if they are unreasonably dangerous. 5 Frumer & Friedman, supra, § 57.01[4], at 57-9. As this court noted in a previous order, "strict products liability requires ... that manufacturers compensate consumers for the damage caused by unreasonably dangerous products, not necessarily that they remove such products from the market." Bartlett, 2010 DNH 131, at 21.

Bartlett has lengthened the chain of causation to include the FDA in an attempt to overcome the lack of any duty on Mutual's part to stop selling sulindac. Nevertheless, the duty problem persists. Bartlett has not presented any expert testimony or other evidence to suggest that a reasonable manufacturer in Mutual's position would have filed a citizen's petition advocating that its own drug be removed from the market, when it simply could have stopped selling the drug on its own. Bartlett argues that Mutual's conduct in filing nine citizen's petitions over the past decade establishes a "standard of care to file citizen's petitions." It is true that a defendant's internal practices can serve as evidence of a standard of care. See, e.g., Hood v. City of Nashua, 91 N.H. 98 (1940). But none of Mutual's citizen's petitions sought the removal of one of Mutual's own drugs, so they do not establish any standard of care in that regard. Indeed, so far as the record indicates, there appears to be no precedent for such a petition.

As if the many problems discussed above were not enough, Bartlett's negligence theory also raises serious federal pre-emption concerns under the Supreme Court's decision in Buckman, 531 U.S. at 348, which held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by" the Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 301 et seq. The claim in Buckman was that the defendant drug manufacturer "made fraudulent misrepresentations" to the FDA in the course of obtaining approval of a medical device, and "that such representations were at least a 'but for' cause of injuries that plaintiffs sustained. ... Had the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." Id. at 343.

The Supreme Court reasoned that such claims "inevitably conflict with the FDA's responsibility to police fraud consistently with [its own] judgment and objectives," and by raising the prospect of state tort liability for failure to communicate with the FDA, would give drug manufacturers "an incentive to submit a deluge of information that the [FDA] neither wants nor needs, resulting in additional burdens on the FDA's evaluation." Id. The Court concluded that "this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." Id. at 353.

While this case involves an allegedly negligent nondisclosure to, rather than an intentional fraud on, the FDA, it raises some of the same concerns identified in Buckman. If drug manufacturers could be held liable under state law for negligent "failure to communicate with the FDA" (which is how Bartlett

describes all of her negligence theories), then there is a very real possibility that the FDA would be "deluged" with citizen's petitions and other correspondence from manufacturers seeking to protect themselves against such state tort liability. That could impede the FDA's efforts to fulfill its regulatory mission in an efficient manner.

Whether Buckman's logic extends to this type of negligent nondisclosure claim is debatable. Some courts have construed Buckman narrowly as applying only to true "fraud-on-the-FDA" claims. See, e.g., Desiano v. Warner-Lambert & Co., 467 F.3d 85, 97 (2d Cir. 2006), aff'd without opinion by an equally divided court, 552 U.S. 440 (2008). Other courts, however, have read Buckman more broadly as encompassing other types of claims that raise similar concerns. See, e.g., Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961 (6th Cir. 2004); Hughes v. Boston Sci. Corp., 669 F. Supp. 2d 701, 712 (S.D. Miss. 2009) (stating that the "Buckman holding did not turn on intentional versus negligent" misrepresentation and calling that "a distinction without a difference"). This court need not choose a side in that debate, given the many other problems with Bartlett's negligence theory, as discussed above. Suffice it to say, however, that Mutual's argument for Buckman pre-emption is not a frivolous one.

In sum, Bartlett's claim that the FDA would have removed sulindac from the market in response to a citizen's petition or other submission from Mutual is largely counterfactual and otherwise based on improbable inferences and speculation. The claim therefore fails for lack of causation. The claim also runs into problems on the element of duty, especially to

the extent that Bartlett is arguing that Mutual should have advocated that its own drug be removed from the market. Finally, while the court need not decide this issue in light of the lack of causation, the claim raises substantial federal pre-emption concerns under the Supreme Court's holding in Buckman, since it is premised on Mutual's alleged "failure to communicate with the FDA."

B. Enhanced compensatory damages

Since Bartlett has not presented sufficient evidence to support any of her negligence theories, this court must proceed to answer the other question briefed by the parties: whether Bartlett can nevertheless recover enhanced compensatory damages on her strict liability claim. Under New Hampshire law, an award of compensatory damages may be enhanced in "exceptional cases" where the defendant's tortious "act is wanton, malicious, or oppressive." Stewart v. Bader, 154 N.H. 75, 87 (2006). An act is "wanton" if the defendant recklessly creates a risk of great harm. See Minion, Inc. v. Burdin, 929 F. Supp. 521, 525 (D.N.H. 1996) (McAuliffe, D.J.) (citing Thompson v. Forest, 136 N.H. 215, 220 (1992)). An act is "malicious" if the defendant has "ill will, hatred, hostility, or evil motive." Stewart, 154 N.H. at 87. An act is "oppressive" if it constitutes an abuse of power. See Walter L. Murphy & Daniel C. Pope, New Hampshire Civil Jury Instructions § 9.14, at 9-17 (1996). It is the plaintiff's burden "to present evidence of wanton, malicious or oppressive conduct." Figlioli v. R.J. Moreau Cos., 151 N.H. 618, 622 (2005).

In the summary judgment ruling, this court concluded that a reasonable jury could award enhanced compensatory damages in this case based on Mutual's

"failure to survey the medical literature for information about sulindac's safety risks," and any other failures that followed from that one, such as a failure to report such information to the FDA. Bartlett, 2010 DNH 112, at 28. But that was before Bartlett submitted her evidence in support of that theory, and obviously before this court concluded that her evidence was insufficient to prove that Mutual's failure to survey the medical literature caused her injuries. See Part III.A.iii, supra. The question is whether that lack of causation, which clearly defeats Bartlett's claim for regular compensatory damages based on that conduct, defeats her claim for enhanced compensatory damages as well.

Analogizing to punitive damages cases from other states, Bartlett argues that enhanced compensatory damages could nevertheless be awarded on her strict liability claim, which alleges that sulindac was a defective product unreasonably dangerous to consumers. It is true that, even though such claims focus on the product itself rather than the defendant's conduct, most courts allow punitive damages to be awarded where there is "proof that a higher level of fault exists than that which supports the actual damage award." 2 Frumer & Friedman, supra, 14.03[1][b], at 14-35 (quoting Racer v. Utterman, 629 S.W.2d 387, 396 (Mo. Ct. App. 1981)). In other words, most courts allow punitive damages where the defendant has acted recklessly in relation to the product, even if that reckless conduct was "immaterial" or legally unnecessary to a finding of strict liability. Id.

But punitive damages are prohibited by statute in New Hampshire, see N.H. Rev. Stat. § 507:16, and the

New Hampshire Supreme Court has made clear that enhanced compensatory damages are different from punitive damages. They are, "as their name indicates, compensatory and not punitive in nature." State v. Hynes, 159 N.H. 187, 198 (2009). They cannot "be awarded as a punishment to the defendant or as a warning and example to deter him and others from committing like offenses in the future." Stewart, 154 N.H. at 88. Nor can they be treated as somehow "separate from actual damages." Nollet v. Palmer, 2002 DNH 136, 7 (DiClerico, J.) (citing Vratsenes v. N.H. Auto, Inc., 112 N.H. 71, 73 (1972)). Rather, they must "reflect the aggravating circumstances of an injury caused to the plaintiff." DCPB, Inc. v. City of Lebanon, 957 F.2d 913, 915 (1st Cir. 1992) (applying New Hampshire law). So Bartlett's analogy to punitive damages is unpersuasive.

Both parties agree that there is no precedent in New Hampshire for awarding enhanced compensatory damages on a strict liability claim. This court need not decide whether such an award is ever possible. All that need be said is that such an award is not possible on the particular facts of this case. It would be inconsistent with New Hampshire law for enhanced compensatory damages to be awarded based on conduct by Mutual that, due to a lack of causation, could not serve as the basis for an award of regular compensatory damages (which is true of all of Mutual's conduct that arguably could be considered "wanton, malicious, or oppressive"). That would make the enhanced compensatory damages "separate from actual damages" and would make them impermissibly punitive in nature. See Evans v. Taco Bell Corp., 2005 DNH 132, 35-36 (DiClerico, J.) ("Because [the plaintiff] has not shown a genuine issue of material fact as to

whether [the defendant's] allegedly wrongful actions caused her claimed damages, she cannot recover enhanced compensatory damages.").[10]

IV. Conclusion

For the reasons set forth above, Mutual is granted judgment as a matter of law on Bartlett's claims for negligence and enhanced compensatory damages.

SO ORDERED.

/s/ Joseph N. Laplante
Joseph N. Laplante
United States District Judge

Dated: September 14, 2010

cc: Keith M. Jensen, Esq.
Bryan Ballew, Esq.
Patrick J. O'Neal, Esq.
Eric Roberson, Esq.
Christine M. Craig, Esq.
Timothy P. Beaupre, Esq.
Joseph P. Thomas, Esq.
Paul J. Cosgrove, Esq.
Jeffrey D. Geoppinger, Esq.
Linda E. Maichl, Esq.
Stephen J. Judge, Esq.
Pierre A. Chabot, Esq.

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[10] Even without the ability to seek enhanced compensatory damages, Bartlett recovered $21.06 million in compensatory damages at trial, which consisted of $1.25 million in past medical expenses (stipulated by the parties), $2.377 million in future medical expenses, $933,000 in lost wages, and $16.5 million in pain and suffering.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v. **Civil No. 08-cv-358-JL**

Mutual Pharmaceutical

Company, Inc.

VERDICT FORM

LIABILITY: Do you find, by a preponderance of the evidence, that Mrs. Bartlett has proven her claim against Mutual for strict products liability?

Yes

(Yes or No)

(If your answer to the Liability question is "Yes," then proceed to the Damages questions on the next page. If your answer to the Liability question is "No," then you must conclude your deliberations.)

DAMAGES: What amount of compensatory damages, if any, do you award to Mrs. Bartlett on her claim for strict products liability? Please state the amounts, if any, for each of the following categories, and then state the total amount on the bottom line. State the amounts in words, not figures.

(1) Past medical expenes:

One million two hundred fifty thousand

(2) Future medical expenses:

Two million three hundred sevety-seven thousand

(3) Lost wages:

Nine hundred thirty-three thousand

(4) Pain, suffering, and loss of enjoyment of life:

Sixteen million five hundred thousand

TOTAL DAMAGES (total of the four categories above):

Twenty-one million sixty thousand

(This concludes your deliberations.)

_____

Foreperson

September 8, 2010

Date

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

KAREN L. BARTLETT, Plaintiff,

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Defendant.

08-cv-358-JL

August 19, 2010
8:15 a.m.

Day 4

TRANSCRIPT OF TRIAL

MORNING SESSION

BEFORE THE HONORABLE

JOSEPH N. LAPLANTE AND A JURY

* * *

Q. Essentially death?

A. Death, yes. And so if you take everything I usually say there's probably a 50/50 chance that someone will survive. Mrs. Bartlett was younger. She was in pretty good health. And so I erred on the side of survival.

Q. Okay. And why do -- why is a burn diagram like Exhibit 132 created, Dr. Schulz?

A. Excuse me?

Q. Why is a burn diagram like what I'm showing you, why is it created?

A. Oh, it's created just as a working record of how much skin is open, which we use as kind of a surrogate for how sick the patient is.

Q. Okay. And this was created on the very day she arrived; correct?

A. Correct.

Q. And who created this, please.

A. Dr. Sabatini I believe.

Q. Okay. And tell us what this means. First of all, are these crosshatches written in by Dr. Sabatini?

A. Dr. Sabatini wrote in the crosshatches and they mean that the epidermis, those are areas where her epidermis has fallen off and she has exposed dermis.

Q. Okay. Up here on the diagram it says TENs with the crosshatches, and is she therefore doing crosshatches everywhere she believes she has TENs?

A. What she meant was epidermal slough there.

Q. Okay. And what does this tell us when it says 42 percent TENs?

A. Well, that's the area of epidermal denudation or where the epidermis was fallen off of her skin.

Q. When you say epidermal denudation, does that mean, does that relate to or not an open wound?

A. That would be an open wound. That is where her epidermis has come off of her dermis. Her dermis is open and exposed.

Q. Okay. So this document would have told you at this time that the assessment was 42 percent of her body was an open wound?

A. Yes.

Q. How does that relate to taking care of her?

A. Well, it relates in multiple ways. Number one, the epidermis is the barrier against bacteria and other microbes. It's the seal that keeps water inside. Without epidermis, exposed dermis is very painful. And so three things right off the bat. It puts her at risk of infection, invasion through the dermis, for which we apply things that kill germs basically. It causes a large fluid loss through her skin, and it requires -- it means that she needs a significant amount of pain medicine.

Q. What, if anything, would this chart that I'm I'm putting the square around have told you, Dr. Schulz?

A. Simply that she had slough around her genital area, anal and genital area.

Q. Okay. And it seems to be more highlighted on the face here than even on the chest. Would you place any significance to that?

A. Well, for the crosshatching, no, it may have been more simply because of the eyes and mouth.

Q. And what is this here?

A. Those are the attempts to -- or those are the estimates of total body surface area involved with the epidermis falling off.

Q. And how do you characterize TEN. Is that to be a certain percent of your body being an open wound?

A. I would characterize it as greater -- as 30 percent or greater of the epidermis falling off.

Q. Okay. Now, on your first note here you write on arrival here adequate airway, excruciating pain. What led you to make that note?

A. Why did I make that?

Q. What led you to write that down?

A. She is in excruciating pain -- she was in excruciating pain, and all patients with this problem are in excruciating pain. Her eyes are raw and weeping. Her mouth is open and weeping. The lining of her mouth and throat is blistering and falling off and bleeding. And her -- 42 percent of her body is experiencing the same kind of symptoms that you would experience if you fell off your bike and scraped your elbow. That's a little analogy, a quarter size pain multiplied by, you know, 150 fold.

Q. How did you attempt to address her pain?

A. We addressed her pain by giving her high doses of narcotics.

Q. Were you involved in this first ophthalmology consult on February 4th?

A. I'm sure that I asked that ophthalmology be called right away.

Q. Why would you have done that?

A. It's very important to have an ophthalmologist following the patient's eyes when they are significantly involved, and they always are with TENs because the lining, the conjunctiva is the affected surface. It experiences the same phenomenon that the skin in the lining of the mouth did. So the lining of the eyelids and the conjunctiva that covers the eyeball gets inflamed and falls off[.]

* * *

mouth and behind the tongue and into the windpipe, there's another way to get in there which is directly through the front of the neck down through the skin,

your windpipe, it's right there and there are safe ways, basically fairly safe ways to put a tube directly through skin and muscle into that airway.

Q. Let's talk about how she was treated. Was she treated in a specialized burn bed at Mass. General?

A. Yes, she was.

Q. 1602 for demonstrative purposes. Let me focus this in. Is this a picture of a burn bed at Mass. General precisely like the one that Karen was treated in?

A. Yes, it is.

Q. Okay. And is that a nurse that treated Karen Bartlett featured in that picture?

A. Yes, it is.

Q. Who is that?

A. That's Frank Ireland.

Q. Okay. Tell us, for those of us who have never seen this, what is this plastic bed called?

A. Well, it's called a bacterial controlled nursing unit.

Q. Why do you use it at MGH?

* * *

Q. Okay. Did you think about whether or not Sulindac caused it when you learned that?

A. Well, when I learned that Sulindac was a new medication that she had been taking and apparently she had taken it every day up until close to the point that she developed this syndrome of Toxic Epidermal Necrolysis, I thought that's it.

Q. Did you consider in your mind other possibilities that might have caused it?

A. I wasn't aware of any other medication that fit that profile.

Q. Let me ask you. If I were to list these things, did you think any of these things could have played a role. A virus or a bacteria?

MR. THOMAS: Objection.

A. No.

MR. THOMAS: He's asking for contemporaneous opinion.

Q. Okay. In 2005 when you were assessing this, Dr. Schulz, could a virus --

THE COURT: He can have an opinion today as long as it's based on his treatment.

MR. THOMAS: Can we approach for one moment?

THE COURT: Sure.

AT SIDEBAR

MR. THOMAS: He can have an opinion today as long as it's the one he expresses as the one he formed during --

THE COURT: Of course. So let's keep it within the white lines. What are you trying to say, then?

MR. THOMAS: That's it. I mean the question was actually do you have an opinion. So I didn't know if we were getting into something new.

MR. JENSEN: This is my fault.

THE COURT: Go ahead.

BEFORE THE JURY

THE COURT: Just rephrase, counsel.

MR. JENSEN: Sure.

Q. BY MR. JENSEN: Did you assess in 2005 what caused your patient's TEN?

A. Yes.

Q. Anything to do with a virus cause the patient's TEN?

A. No.

Q. Have you heard of things like microplasma pneumonia?

A. Of course, I've heard of them.

Q. Did that cause it?

A. No.

Q. Ever heard of citomegalovirus?

A. I've heard of it.

Q. Epstein-Barr virus?

A. Yes.

Q. Any of those things cause Karen's TEN?

A. No.

Q. What about a possible bacteria?

A. No.

Q. Okay. What about Chinese food?

A. No.

Q. What about -- what's gastroenteritis, Dr. Schulz?

A. Well, basically gastro means stomach and entero means the gut below the stomach, and it is means sick or inflamed, so you put those together, it means a bellyache somewhere from top to bottom.

Q. Okay. Do infections and other things cause minor forms of SJS potentially?

A. Definitely.

Q. Okay. And like microplasma pneumonia, is that one of them?

A. Yes.

MR. THOMAS: We're back to contemporaneous.

THE COURT: You have to be careful about --

Q. Let's unless I indicate --

THE COURT: Let's be careful.

Q. Dr. Schulz, unless I indicate otherwise would you be willing to solely provide testimony as to what you found --

THE COURT: No, no, no. Pose the question. Don't ask him to stipulate to something and just go off on a tangent. Ask the questions correctly.

Q. Fair enough. What about air pollution. Did that cause Karen Bartlett's TEN?

A. No.

Q. What about her genetics?

A. There are genetic predispositions in some populations, but those have been defined in Han Chinese with certain medications and other things, so for Karen, no.

Q. Okay. And let me put something else here, one more category, called everything else in the world. Everything else in the world other than Sulindac. And did you think about how likely it was that Sulindac was or was not the cause of Karen Bartlett's TEN in 2005?

A. Absolutely.

Q. Okay. If you added all these things together, Dr. Schulz, virus, bacteria, Chinese food, gastroenteritis, air pollution, genetics, and everything else in the world, what did you think in your mind in 2005 as to what was the likelihood that any or all of these things could have caused Karen Bartlett's TEN?

A. I felt she had taken Sulindac and that the timing fit her Toxic Epidermal Necrolysis and the chance that something besides that causing it was less than one percent.

Q. Therefore, what did you think the likelihood was that Sulindac caused your patient Karen Bartlett's TEN?

A. Greater than 99 percent.

Q. Let's talk about Chinese food. Did Chinese food come up in relation to Karen's treatment?

A. Well, yeah, I mean it came up because I remember when they called from Tufts, oh, well, we have a lady that ate Chinese food and she got TENs. I'm like, you know, that was a big joke on the unit, oh, you better watch out, not go to Chinatown. So that's how it came up originally.

Q. Okay. Who is doctor, let me find the name -- did you originally ask a cardiologist to look at Karen Bartlett for a SVT?

A. We did. Cardiology did see her.

Q. And did you come to learn that something in the records had indicated that she had a history of either NSAIDS or Chinese food as a result of her biopsy

* * *

[A]voiding medications, she's probably okay for medications but definitely not anything that has a

chemical structure like Sulindac. I would be very leery of that.

Q. What's a positive rechallenge?

A. A positive rechallenge is when someone that has had Toxic Epidermal Necrolysis or Stevens-Johnson reaction to a drug is given it again.

Q. Has that happened to any of your patients?

A. Yes, it has.

Q. Is that exactly why you're making clear to Karen Bartlett here that she should never take Sulindac again?

A. Absolutely.

Q. Now, you also listed it should say NSAIDS on her bracelet. Is Sulindac an NSAID?

A. Sulindac is an NSAID.

Q. Why did you have her list all the NSAIDs if you thought it was Sulindac?

A. Because the Sulindac -- because she went through hell on earth and I want to establish as big a boundary around the causative medications as I can, so list all NSAIDS. Then if somebody doesn't get the Sulindac -- it gives people two references if they are thinking about giving her something. Don't give her any NSAIDS, and that would cover Sulindac.

Q. Not by name but by type of healthcare provider, what other types of healthcare providers worked with you in the care and treatment of Karen?

A. Nurses, occupational therapists, physical therapists, other physicians, physician consultants, and dietitians, sometimes we call them nutritionists,

and chaplains, and I'm sure I'm leaving somebody out, respiratory therapists.

Q. How often, if at all, would you have meetings with some or all of these other team members to discuss Karen's treatment?

A. We had formal meetings on a weekly basis and we met with most of her other caregivers on a daily basis.

Q. What's this I'm showing you? It's Exhibit 39 for the record.

A. That is a medication order sheet, order transcription sheet. So that's the record of orders that have been introduced into practice with the patient.

Q. Okay. And here it says adverse reaction to drugs, et cetera, and it's written in Sulindac. Do you see that?

A. Correct, I do.

* * *

Q. So please explain, if you can, how it was possible for your patient, Ms. Bartlett, if she stops taking Sulindac on or about February 1st let's say. You see her February 4th, and you're telling us her skin is getting worse. How is that possible if she stopped taking the Sulindac on February 1st?

A. So the answer, any answer that you get to that would be speculative, but because the syndrome happens in response to a medication and there is -- the absolute standard of care is to stop the medication that you think caused it once the syndrome arises. But why the syndrome develops and how far it goes and how bad it gets is something that we don't understand and we can't control. There are -- it's hypothesized that drugs that stick around in the body longer will, you know, wear -- people will continue to react to them

longer. But the truth is that we really don't know. I mean, the process has started, and we don't know when it's going to stop, and we don't know why it stops when it does.

Q. Okay. Is this your note here that you signed at the bottom, Dr. Schulz?

A. Yes, that's my note.

Q. And does part of this note say 60 to 65 percent TBSA?

A. Yes, it does.

Q. What is TBSA?

A. Total body surface area.

Q. And so therefore has she gotten worse from 5 percent of her skin being an open wound to 60 to 65 percent of her skin being an open wound?

A. Yes. More of her epidermis has fallen off.

Q. And would you have reviewed this gynecology consult which says greater than 60 percent involvement in her skin?

A. Yes, they would have gotten that information from me in fact.

Q. And would you have reviewed this infectious disease consult that says greater than 60 percent TBSA?

A. Yes.

Q. Why would you have reviewed it -- what is an infectious disease consult?

A. Well, an infectious -- infectious disease is a subspecialty of internal medicine, and they specialize in infections and in the treatment of infections, and

Karen had some fairly serious infections, and so the infectious disease consult is someone that helps us in deciding what the best way to treat that is.

Q. What were you doing to combat this worsening problem, the 42 percent to 60 to 65 percent of her skin being an open wound?

A. There is nothing that you can do to stop the progress of the epidermis falling off. So what we're doing is in the midst of this we're keeping her alive. We are breathing for her. We are controlling her pain. We are replacing huge fluid losses that evolve into blood losses through eroded skin or eroded wounds. So we were providing supportive critical care, and that's what you can do.

Q. You told us you concluded that Sulindac caused her TEN. Did Sulindac cause this process to go from 42 percent to as high as 65 percent after she stopped taking it?

A. Absolutely, Sulindac caused the TENs. The TENs is something that happens in response to taking Sulindac. Where she ends up in terms of her total body surface area of epidermal slough is a direct consequence of her having TENs. We don't know why some people belong to a hundred percent slough and some people go to 65 and some people go to 35.

Q. You mentioned infections. What was the first significant infection she had, if you remember?

A. I've got to look at the record. I think that it was a staph, I think she had a staph infection in her blood, but I need to look.

* * *

Q. Let's take a look at your notes of 2/9 now, February 9. Tell us how she's doing then, please.

A. So, well, on 2/9 under -- so under infection I've written that she's not on any antivirus and she's afebrile, so I would say at that point I would say she's infected.

Q. Okay. Were you involved here, doctor, with -- what procedure was this on February 9th?

A. Oh, it looks like -- so the procedure was putting in a central line which is a large IV into her left subclavian vein, and yes, I was involved.

Q. And next day, February 10th, you're involved for 35 minutes. How is she doing then, please?

A. Looks like she is fairly stable.

Q. Okay. And you say Aquacel Ag wounds. What's that?

A. Aquacel Ag is cellular cell with silver dispersed through it so it can absorb fluid coming off the wound and the silver kills germs, and so it's basically, you can think of it as an antibiotic dressing that you would put on open wounds.

Q. Is pig skin called xenograph?

A. Pig skin is called xenograph.

Q. Was pig skin ever used on Karen Bartlett?

A. Yes, it was.

* * *

Q. I'm going to show you a document, 140 for the record, and it's a chart of Karen's pain medications given while at Mass. General, and I'm going to focus in on that main point perhaps. And it says morphine

sulfate number of times given 48. What's morphine sulfate?

A. Well, morphine is a narcotic and so that's it.

Q. It says Dilaudid given 85 times. What is that?

A. Dilaudid is -- its generic name is hydromorphone, so it's a morphine-like narcotic. It's more potent than morphine.

Q. Lorazepam six times, what's that?

A. That's benzodiazepine. It's Ativan which is an anxiety drug.

Q. Valium given 70 times, what's that?

A. Valium is another benzodiazepine. It's one of the drugs for anxiety and amnesia.

Q. But why are you giving a drug for anxiety to a person who is hopefully asleep if you will?

A. She's not. So the medically induced coma, the patient is not able to respond, but the assumption is that they are on a minute by minute basis, they are experiencing their surroundings, and we need to suppress both anxiety and the memory. So we don't want memory of this horrendous experience, and that's why we're giving the drug.

Q. Okay. And the next line says methadone given 90 dimes. What's that, doctor?

A. Methadone is another narcotic and it's actually a great -- it's a great long acting, long half-life narcotic that you can use to transition people who have been on continuous narcotics, you can transition them to taking a pill every so often that maintains a level of narcotics in their bloodstream.

Q. And then you give or Versed was given 146 times. What's that, doctor?

A. Versed is another benzodiazepine.

Q. What would you and your team do in determining on a daily or hourly basis how much of all these pain medications to give?

A. Well, so, well, number one, she's on a continuous drip of medications. She starts off, after she's intubated, we pick a number that we think will maybe be adequate, and then we use clinical indices to tell whether we're doing okay. The ones I mentioned before are her reactions. Crying, grimacing, you know, evidence of agony in the face, increasing heart rate and increasing blood pressure. The other things are whether or not she's fighting the ventilator and -- what else, that's it. Things like that are what tell us whether we're doing a good job. And if she seems to be in agony, and this is really where the critical care nurse is extremely important, that person is spending the most time with her during the day and night, then we increase the medications. And if she seems to be doing okay, then we might try to cut back a little bit. Every day we're trying to fiddle with these things so that we get just right, not too much, and definitely not too little. But we know that they have to come off at some point. So if we don't have to go way up, we don't want to. And if we go way up on some of them, it could affect her blood pressure adversely. So that's another reason not to.

Q. 1379A for the record. It says here and it's on February 15th, Dr. Schulz, that in part says dressing changes remain painful. What does that tell you about whether she's experiencing pain just about nine days into this?

A. She's experiencing pain.

Q. And addressing change, what's that?

A. Well, so she had been on this -- at that point over half of her body is a big open wound and so a dressing change on that, I mean, they are going to be

* * *

Q. So please explain this to us. We have 60 days here listed, and on some of the days you see on the first page, I'll count 3, 5, 8, 9, 12, 14, it looks like 16 packed cells on different days, she got packed cells. What is that?

A. Correct. Packed cells are what people conceptualize as getting a blood transfusion. So what happens is donors give blood and then they put the blood in a centrifuge that spins it around and cells mostly fall out and they take the plasma off of that and we use those components separately. So packed cells are just packed red blood cells but are close to twice as concentrated as the blood cells in your own bloodstream would be.

Q. And why does she need all these blood transfusions of packed red blood cells?

A. Because she is bleeding a lot from her wounds. And another reason is because the inflammatories that the injury or illness creates suppresses formation of her own red blood cells.

Q. Quantify it for us to the extent you can, please, Dr. Schulz, again 660 or 330, what does that mean in terms of how much blood she's had and how much blood she's lost?

A. Well, I think that those are volume measurements of cc's or milliliters. So a liter is about a quart, right,

so if you add -- the first two sets of transfusions, 660 plus 660, that's one and a quarter to one and a half quarts. Now, these are packed cells, so the blood that she's losing is about half as concentrated as the packed cells. So if we give her 660 cc's of packed cells, then translating backwards she lost about one and a quarter quarts of blood to get that much blood back. And the average adult has about five quarts of blood in their body -- wait, let me think about that. Yeah, that's right.

Q. Okay. So, what you just taught us is that Karen was losing as much as approximately a fifth of all the blood in her body on each of these 18 times?

A. She definitely could in a single dressing change. It's going to be variable, but yes, the simple answer is yes.

Q. And what is this -- does this stand for fresh frozen plasma, Doctor?

A. Yes, it does.

* * *

Q. BY MR. JENSEN: Did you last see Karen in October, 2005, Dr. Schulz?

A. Yes, I did.

Q. Did you learn what I just mentioned before October, 2005?

A. Yes, I did.

Q. So what you said after your treatment, you were talking about after the second hospitalization?

A. After the acute -- the first hospitalization.

Q. Okay. So while you were still Karen Bartlett's treating physician, did you learn that she was diagnosed with Post-Traumatic Stress Disorder?

A. Yes.

Q. Did that surprise you?

A. No.

Q. Why not?

A. Karen was a well human being. She had a weekend in the city and then she gets rapidly incredibly ill. She has a conversation with me that I'm going to intubate her and she may be dead and she may not, you know, this may be the end of it. And then she goes into treatment which hopefully she doesn't remember much about but when she emerges, things are not pleasant. She emerges, she has open wounds, her eyes, she can't eat, she still has pain, all of these experiences are what she's living with when she's awake on a burn unit. Then she goes to rehab and she comes back four days later and in the office she almost has a respiratory arrest, and I readmit her. And the process goes on. Does it surprise me that she has Post-Traumatic Stress Disorder? No, not at all.

Q. In relation to your care and treatment of Karen Bartlett, is there a relationship between the Post-Traumatic Stress Disorder that you understood she was diagnosed with and the same disorder that our war heroes are diagnosed with when they return from combat, same disease?

MR. THOMAS: Objection.

THE COURT: No, it's just not relevant.

Q. Tell us what your understanding of what this diagnosis meant from your perspective as her attending physician.

MR. THOMAS: Objection.

THE COURT: You're asking him what this -- what are you asking him, what PTSD is?

Q. What's your understanding of what Post-Traumatic Stress Disorder is from your perspective

* * *

getting a ventilator. That's how we define intensive care beds.

Q. To your recollection approximately what portion of Karen's first 70 hospital days would she have been in a burn care ICU bed?

A. I think it was about 80 percent.

Q. Okay. And you mentioned that she had plugging in her tracheal line when she came back in; is that correct?

A. In her tracheostomy.

Q. What does mean?

A. She was dehydrated and she had a huge amount of secretions still, and she wasn't swallowing very effectively. That could have contributed from run down from her throat, but she had a bunch of secretions in there and they were very thick and plugged and they just, I mean, it just plugged off. She was trying to cough out a secretion through the tracheostomy tube and it plugged.

Q. Okay. The jury heard Dr. Kim testify yesterday about bronchoscopies. Have you heard that term?

A. I have.

Q. Did Karen have bronchoscopies?

A. She had bronchoscopies.

Q. Why were they needed?

A. Because the -- I think I mentioned it earlier that, so number one, the pulmonary function on the ventilator and her x-rays were getting worse, and she had the dying off of the lining of her airways, so she was getting pneumonia, and part of the reason for it was that she was developing all of these plugs in small airways, and the bronchoscope is an instrument that we can, number one, put in and assess what's going on and whether she has plugging things in there, and number two, it has a suction device on it so we can suck out plugs, so that's why she got the bronchoscopies.

Q. Now, we introduced the topic of septic shock. Now, please relate to us what you remember about Karen Bartlett's septic shock and how big of a threat it was to her.

A. Well, I remember that she had two major septic episodes. One was probably ten days. I think you showed me the record where we were talking about staph. And then we treated that and she had another fairly bad septic period. During those periods, if not for blood pressure elevating medication, she would have been in shock. Coincident with one of those episodes her lungs were bad enough that we had to chemically paralyze her to eliminate any resistance that she would have to the ventilator so that we could get adequate oxygen. And so she was extremely sick and these are the cases without the antibiotics and without the blood pressure elevating medications, she would not survive.

Q. Were you ever fearful that she would die?

A. Every day for the first, you know, I'm always afraid that a patient like Mrs. Bartlett is going to die, and I would say, you know, the first 30 days until, until they are out of the intensive care unit, I am worried about them, I'm intensively worried about it in the first three weeks to a month.

Q. Could you at some point predict -- well, in the first two weeks could you tell if she was getting better, getting worse, or whether her risk of dying was hopefully improving or not?

A. Well, she was getting worse. We expected her to get worse. When she came in, we expected her to get worse. And, you know, the risk of dying, well, that's a moving target, the subject to a lot of opinions and, you know, how the patient is doing, but what we know is that she comes in bad and she's getting worse and she could die, and we don't want that to happen. That's what we know on a daily basis. And it's not like we sit around and say, oh, she has a 55 percent chance today. No.

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
KAREN BARTLETT, Plaintiff
v.
MUTUAL PHARMACEUTICAL COMPANY, INC.,
Defendant

08-cv-358-JL
August 20, 2010
8:20 a.m.
Day 9 - Morning Session

TRANSCRIPT OF JURY TRIAL BEFORE THE HONORABLE JOSEPH N. LAPLANTE

* * *

[P]atient adherence to directions for use is crucial to the drug's effectiveness. You may consider those FDA regulations to have been proven to you. Mr. Jensen, you may proceed with Dr. Tackett.

MR. JENSEN: Thank you, your Honor.

DR. RANDALL TACKETT

CONTINUED DIRECT EXAMINATION

BY MR. JENSEN:

Q. Good morning, Dr. Tackett.

A. Good morning.

MR. JENSEN: Good morning, ladies and gentlemen.

Q. Dr. Tackett, when we left off when you were on the stand, sir, we had just introduced the topic of your selection by the 51 Attorneys General related to your area of expertise. Do you recall that we were discussing that?

A. Yes.

Q. Okay, and did you receive a grant from the 51 Attorneys General of America?

A. Yes, sir. I did.

Q. Did you apply for that grant?

A. Yes, sir. I put a proposal in.

Q. What did you do?

A. Basically, I had to write a proposal that outlined what we planned to do, and that was submitted along with our credentials, which was basically our curriculum vitae.

Q. Okay. Was there an interview process?

A. Yes. We were telephone interviewed, yes.

Q. Do you have knowledge of how many applications were filed?

A. I do not.

Q. Okay, and what did you propose to do in your application?

A. We proposed to develop a curriculum that basically would teach physicians, prescribers and consumers about various aspects of the drug approval process, how drug safety is evaluated and incorporated into the label. We also talked about the difference between brand drugs and generic drugs, the difference in approval process there, and we also talked about issues concerned with advertising and how information is presented as far as advertising goes. We also talked about the definition between what is -- what we refer to as off label prescribing, which is basically when a physician writes for a prescription that is not an approved indication in the label.

* * *

[H]e wants to -- in the report, Exhibit 419, that he thinks undermine the conclusion, he can certainly bring them out, and if you want to use it to rehabilitate, that's fine, but at the outset reading it into the record I don't think is proper.

MR. JENSEN: May I ask: What, if any findings existed in the report that support or relate to your opinion?

THE COURT: Yeah, I think it's fine, but to me it's more proper for him to know the findings and to testify about them than it is to read them into the record. There's a difference; all right? Okay.

(CONCLUSION OF SIDEBAR)

THE COURT: Sir, I see you standing up. It reminds me. Are you hearing better now?

THE JUROR: Yes. Thank you.

THE COURT: Okay.

Q. Please tell us, Dr. Tackett, about this congressional assignment and what it was all about.

A. Well, basically, this subcommittee was convened and reviewed --

Q. By who?

A. Sorry. This was a subcommittee on oversight investigation and it --

Q. When was it done, please?

A. 2008.

Q. Okay.

A. And the chair of this was Gail Cassell and basically was looking at science and mission at risk, the FDA's self-assessment.

What's sort of unique about this subcommittee was the composition of the committee had a wide range of people from academia, from the drug industry and from government agencies. So it had a broad base from which to evaluate the FDA.

So again, remember, we started with concerns in 1998, and now we're up to 2008, and a couple of the things that they point out is it became rapidly apparent that the FDA suffered from serious scientific deficiencies, and it also stated it wasn't in a position to meet the emerging regulatory responsibilities.

They're basing this on the fact that we're getting more drugs coming out. The drugs are becoming more complex. We have mixed dosage forms. We have biologicals. We have a number of different types of drugs. We have new information emerging with regard to things like genomics and those type of things, and so they simply -- you know, they summarize and say that we have found quite simply the demands of the FDA have soared over the past few decades and resources haven't, and they specifically found a few points with regards to deficiencies.

The first one was the FDA can't fulfill its mission because its scientific base has eroded and basically the structure is weak.

MR. THOMAS: Objection, your Honor. He is reading from the document.

THE COURT: Doctor, you can testify to your opinion based on the document, but reading from the document for the record is wrong.

A. Thank you. They basically said they can't monitor adequately the drugs that are out there and they don't have enough resources. So that's the committee's finding, which basically says that the FDA has serious deficiencies.

Q. Based upon this -- the testimony you just referred to is in 2008, correct?

A. Correct.

Q. The report was done when that related to the testimony that you just referred to?

A. The report was done earlier. I'm trying to remember when it was. I can't remember the exact date when it was done.

Q. Have you actually seen the entire FDA's science and mission at risk that relate to that?

A. I have.

Q. What, if any, finding was there regarding that analysis of the FDA's resources and staffing as it pertains to whether or not injuries and deaths of Americans are at stake as a result of the FDA's under resourcing?

A. Basically, what they concluded was because of this under resources and overwhelming workload that's coming in, that that was putting America, in general, at risk for death, and that included not only drugs but also the food supply.

Q. Were there any findings relating to specifically that injuries and deaths overwhelming the regulatory system are certain?

A. Yes. That was, in fact, their statement.

Q. How, based upon your review of this material, was there a conclusion of a subcommittee appointed by the U.S. Congress and --

THE COURT: You can ask him if there's a conclusion regarding a given topic. Don't lead him, is there a conclusion, and describe the conclusion and have him adopt it. If there's a conclusion about a topic you want to ask him about, let's ask about the topic. Let's not announce the conclusion and have the witness either accept or reject.

Q. How does that relate to the question of whether or not the FDA has sufficient resources and staffing to protect Americans from 10,000 to 12,000 drugs?

A. Basically, since they are supposed to be monitoring the safety, they don't have the resources and they have too much work to do and things are going to slip through the cracks, and so the conclusion is that people are going to get hurt.

Q. Give us an idea of who served on this subcommittee and what their qualifications were to come up with this conclusion that American deaths are certain as a result of an overwhelmed regulatory system.

A. Well, the subcommittee had a Nobel laureate, it had leaders from academia, it had leaders from industry, it had leaders from other governmental agencies. All of those individuals were recognized, and that was stated in the Salisbury testimony.

Q. Was there also in the topic covered of whether or not the FDA suffers from serious scientific deficiency relating to drug safety?

A. Correct.

Q. What was the analysis there?

A. Basically, you look at the scientific deficiency, do they have the personnel to cover it, and the personnel they have -- are they able to keep up with the emerging new science.

I mean, think about the PDRs here and how they've changed in size. That's just one aspect of the information. As we get new science -- for example, we've learned a whole lot about different enzymes and so forth that has to be incorporated. So there's a tremendous amount of new information that's coming up.

Q. What about the proposition that's why we go to medical school, you know everything in those books?

A. The thing is that -- it's like we tell our students right now. I tell my students coming in first day of class, the volume of material that you have to know is going to be huge. What you need to be able to know is where to look for it, and you need to be able to know how to interpret it. So to sit there and think that someone can memorize everything, for example, in a simple PDR, it's not going to happen.

Q. Did the subcommittee appointed by the U.S. Congress also address whether or not the FDA has significant information technology deficiencies?

A. The IT -- we saw it this morning with regard to the television here. We've become so used to processing more information using technology, and one of the big things that emerged was that the IT capabilities of the FDA was subpar. In fact, one of the things they mentioned was it was hard to even keep their e-mail programs running.

When you have a lot of information that's being transferred and used and moved and analyzed electronically, you have a deficiency in that, then that also adds to risk.

Q. Was there any discussion by the committee as to the topic of whether or not the risks of a debilitated FDA are incalculable to American health?

A. Yes. I mean, basically, we know they're subpar, and the question is -- we know they're overloaded so the question becomes -- with all new information and more information coming in, the reality of it is that having a subpar system that is monitoring safety is going to impact the quality of safety that you can provide.

Q. At this congressional review we're talking about of the FDA by this subcommittee they appointed was there any discussion of whether it was the smallest biggest FDA review ever done?

A. This was considered the most comprehensive review that was done.

Q. Ever?

A. Yes.

Q. How does this largest, best review, as they concluded, of the FDA -- do you agree with the conclusions that American lives are certain to be lost as a result of an underfunded, understaffed FDA?

A. I believe so, yes.

Q. Then what's the solution?

A. Well, the solution is basically there needs to be increased staffing, increased resources put towards the FDA, and that's the easy answer.

The other thing you do is that you communicate as best you can to physicians and other people using drugs so they're on alert, but ultimately it comes back to the FDA is getting the information and you're just going to have to have more resources put there.

Q. Do pharmacologists in your area of expertise, Dr. Tackett, regularly and customarily rely upon a subcommittee report assigned by the U.S. Congress to evaluate a question like this?

MR. THOMAS: Objection.

THE COURT: Just rephrase.

Q. Do experts in your field customarily and regularly rely upon a document like the FDA's science and mission at risk to evaluate what we're discussing?

A. Yes. Because we're basically -- what we're looking at -- we look at pharmacology. We look at how drugs produce their actions, but it also is these drugs are going into people and so how we get to people is important. So these reports, as far as if there's a deficit there, are important to us as far as -- especially teaching my students to be aware of that.

MR. JENSEN: I move to -- Exhibit 419 is marked for identification. I move to publish it to the jury.

MR. THOMAS: Objection.

THE COURT: I'm inclined to overrule it, but do you want to argue it?

MR. JENSEN: Here?

MR. THOMAS: Yes.

THE COURT: Sidebar. You know what? It's a good time for the morning break. Let's take the

morning break. We don't have to do it at sidebar. We'll take the morning break.

(IN COURT - NO JURY PRESENT)

THE COURT: I want to give the reporter a break, too. Somebody hand me the exhibit.

MR. JENSEN: May I hand you my copy, and get another copy?

THE COURT: Sure. Actually, I have the exhibits.

MR. JENSEN: Yeah, you should have it.

THE COURT: Do you need a break?

THE WITNESS: Yes.

THE COURT: Take it. You have fifteen, twenty minutes.

MR. JENSEN: I'll give you my work copy, your Honor, while I look for that.

THE COURT: Yes.

MR. JENSEN: I found the original for you, your Honor.

THE COURT: The objection is to publishing it to the jury. By publishing it to the jury you mean what, putting it up on the ELMO?

MR. JENSEN: Yes.

THE COURT: What's your objection?

MR. THOMAS: My objection is the document -- all of the objections stated previously, obviously.

THE COURT: Why don't you remind me what those are.

MR. THOMAS: Well, this is a document that is out of time. It's forward looking. It contains a great deal of information that is not relevant to any of the

matters in this matter -- in this litigation. There's also no evidence that there was any shortcomings of the FDA as they related to Sulindac, with regard to NSAID, with regard to the approval process for any of those.

THE COURT: That doesn't matter. I mean, part of the evidence you're relying on, that this was a -- that this drug was not unreasonably dangerous and that its warning was -- the presence of the warning and the efficaciousness of the warning was sufficient, is that the FDA approved it, and so evidence about the FDA's ability to make that approval is relevant.

He's not asking to admit it as a full exhibit, which he potentially could because it's not hearsay, so it's -- the question is whether it's too prejudicial, and by publishing it he's only going to elicit certain bits of it that were relied upon by the expert, it's hard to know exactly what right now, but it's just a matter of keeping him to what is not prejudicial, it seems to me.

MR. THOMAS: Your Honor, my last comment was that a document that he shouldn't be reading into the record is now going to be displayed for him to read into the record, and either plaintiff's counsel is going to read it or the witness is going to read it and --

THE COURT: But it's not hearsay. I mean, in other words, I'm saying a properly redacted version of this if a foundation was laid might even be an admissible exhibit.

MR. THOMAS: It is hearsay, your Honor.

THE COURT: It's not hearsay. It's 803(8). It's a government report. It's not hearsay. It doesn't mean it's been authenticated or any of that, but it's not hearsay. How is it hearsay?

MR. THOMAS: The fact that in the report -- there is much within the document that is hearsay.

THE COURT: Well, it's a government report -- I'm looking at 803(8). It's a report setting forth, "(c) In civil actions or proceedings factual findings resulting from an investigation made pursuant to authority granted by law unless the sources of information or other circumstances indicate lack of trustworthiness."

I mean, look, he's not asking to submit it as an exhibit anyway so let's not have an argument we don't need to have. The question is can he display -- are you now?

MR. JENSEN: After I was going to publish it[....]

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
KAREN L. BARTLETT, Plaintiff
v.
MUTUAL PHARMACEUTICAL COMPANY, INC.,
Defendant
08-cv-358-JL
August 20, 2010
1:00 p.m.
DAY 5 AFTERNOON SESSION
TRANSCRIPT OF TRIAL
BEFORE THE HONORABLE JOSEPH N.
LAPLANTE AND A JURY

* * *

Q. And what type of expertise, if any, is lacking in this regard according to these findings?

A. According to the findings they did not have the adequate manpower or expertise in that area to basically monitor and analyze data coming in with regard to drug risk and benefit.

Q. You mentioned that this was the largest review ever done of the FDA?

A. Yes.

Q. What is your knowledge as to why there hadn't been significant prior reviews of the FDA?

A. Well, the issue had been is that had been tracked, but there had not been a lot of concern. This really came up as a result of some concerns with drug safety that emerged.

MR. JENSEN: Permission to publish 861 we discussed, your Honor?

THE COURT: Yes.

Q. BY MR. JENSEN: Is 861 another document reviewed this time not by a subcommittee appointed by Congress, but this time by the Government Accountability Office?

A. Yes, it is.

Q. What is the Government Accountability Office?

A. It's basically sort of the auditors of different government operations.

Q. Okay. It's entitled Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process. Do you see that, sir?

A. I do.

Q. Okay. What does that mean, Postmarketing Decision-making Process?

A. Once a drug gets on the market it then goes to the postmarket assessment. So anything prior to it going on the market it falls under premarketing, and once it goes out into the public, that's the term postmarketing. As I mentioned to you earlier today, the necessity is when you're starting to give that drug to real people under real circumstances, then we're going to start seeing or have the potential of seeing issues, side effects, that may emerge that can significantly impact that drug safety. So postmarketing basically is evaluating that, and the decision-making process is basically the deciding of whether there is a risk or whether the drug should be withdrawn or whether there should be label changes, those type of things.

Q. Did this report from the GAO actually assess certain drugs that had been withdrawn?

A. Yes, they used actually four case studies for that.

Q. Did it assess whether or not they were withdrawn soon enough?

A. Yes. The general consensus was it was not.

Q. Did it assess whether or not the FDA had sufficient expertise and resources to figure out whether or not drugs should be withdrawn sooner?

A. Yes. They used those four case studies to show that they didn't.

Q. And what were the four case studies they used?

MR. THOMAS: Objection, your Honor.

THE COURT: That doesn't make much difference. Move on.

Q. Here on page one it says the FDA lacks clear and effective processes for making decisions about providing management oversight of postmarket safety issues. Is that kind of what the title was all about?

A. Yes.

Q. And does that relate to what we discussed earlier with you, Dr. Tackett, about the fact the drug can be on the market decades and potentially still need to have important risk/benefit analysis made?

* * *

Q. Have you -- did you review any information or data from a document from the Institute of Medicine of the National Academy of Science?

A. I did.

Q. And how did it relate to your -- how does it relate to your opinion in this regard?

A. That document came to the same conclusion, is that there was problems with postmarketing assessment of drugs.

Q. Have you found consistency through a number of different sources as to the position that the FDA is underfunded and understaffed to monitor the safety of 10 or 12,000 drugs?

MR. THOMAS: Still leading, your Honor.

THE COURT: Yeah. Ask open-ended questions.

Q. Tell us about all the data you reviewed in relation to this question whether or not the FDA has sufficient resources to monitor 10 to 12,000 drugs.

A. When you basically look at the volume that's coming in, when you look at the, for example, the number of drugs, you look at management of the Adverse Event Reporting System, and you look at the limited resources and turnover that the FDA has had with regard to its personnel, it's my opinion and I think many others that basically it is, it's an organization that's quite associated with it?

A. It did.

Q. Did the New England Journal of Medicine article speak to that?

A. Yes, it actually gave the number.

Q. How many reports of SJS and TEN did Isoxicam have?

A. 13.

Q. And what is your conclusion as to the primary basis for why Isoxicam was withdrawn from the market?

A. Because of the 13 reports of SJS and TEN.

Q. Is there any published literature that pertains to how many reports of SJS and TEN Sulindac has been associated with at any time?

A. Yes.

Q. And what is that?

A. When you say that?

Q. What is the publication?

A. The publication is by Mockenhaupt.

Q. Okay. And how many reports of SJS and TEN did Sulindac have associated with it?

A. 89.

Q. How many NSAIDS in that publication had more SJS and TEN reports associated with it than Sulindac?

A. I believe there was no others that had that many.

Q. Sulindac had the highest number of SJS and TEN?

A. Correct.

Q. Why are 13 reports of SJS and TEN, in your opinion, sufficient to warrant taking the drug off the market?

A. Two reasons. One, it's a very rare disease. And when you have that -- and plus it's a very deadly disease.

Q. Have any other NSAIDS been taken off the market other than Isoxicam?

A. Yes, there have been several.

Q. Okay. What other ones have there been?

A. Are you talking about just taken off the market in general?

Q. Yes.

A. Okay. There's approximately ten that's been taken off the market.

Q. Let's go ahead and give a list, please.

A. There a drug called Ibufenac.

THE COURT: This is going to be a little difficult for the reporter, so if you can spell them it would be helpful.

A. I-B-U-F-E-N-A-C.

Q. Is that drug in the market everywhere in the world?

A. That was only in the United Kingdom.

Q. Okay. Any other drugs, any other NSAIDS that have been taken off the market?

A. The next one would be Benoxaprofen. B-E-N-O-X-A-P-R-O-F-E-N.

Q. And the third?

A. Zomepirac acid. Z-O-M-E-P-I-R-A-C acid. Then there's Suprofen. S-U-P-R-O-F-E-N. Isoxicam. I-S-O-X-I-C-A-M.

Q. That's the fifth NSAID?

A. That's the fifth.

Q. Okay.

A. Bromfenac. B-R-O-M-F-E-N-A-C. Seventh one would be Bextra. And then there's Oxyphenbutazone. O-X-Y-P-H-E-N-B-U-T-A-Z-O-N-E. Fenclofenac. F-E-N-C-L-O-F-E-N-A-C. Then Feprazone. F-E-P-R-A-Z-O-N-E.

Q. Ten different NSAIDS?

A. Correct.

Q. And have you assessed which ones, if any, other than Isoxicam which you told us were taken off the market primarily due to SJS and TEN?

A. Bextra, Oxyphenbutazone, Fenclofenac and Feprazone.

Q. Five of the ten; correct?

A. Correct.

Q. Okay. Why have so many NSAIDS been taken off the market starting with this, with SJS and TEN?

A. I guess the reason would be NSAIDS is a class of one of the highest causes of SJS and TEN.

Q. Does that relate to why there are so many left in the market?

A. Yes. I mean basically the ones that are left on the market have a better risk/benefit profile.

Q. Do all of them? I'll withdraw, your Honor.

THE COURT: Yes. And the last answer, the last answer is stricken. You are to disregard the last answer to the last question, that those left on the market having a better risk/benefit profile.

MR. THOMAS: I will take that answer.

THE COURT: Unless you'd like to have that in.

MR. THOMAS: I'll take that answer.

THE COURT: Okay. You may consider the evidence that the ones that are left on the market have a better benefit/risk profile.

MR. JENSEN: I won't ask the converse, your Honor, I'll move on.

* * *

Q. Explain to us the relationship between being safe and effective one day and being withdrawn the next day if you can, please, these ten drugs we're talking about now.

A. Basically as we talked before this morning, drug safety is emerging. So if a drug is approved and once it gets out into the market, we start seeing increased Adverse Event Reports and literature being published about that, that's going to impact the risk/benefits of the drug.

Q. Okay. So if I hypothetically showed you a letter right now from the FDA that said Sulindac has been deemed safe and effective, how would that relate, if at all, to your risk/benefit analysis of Sulindac?

A. Basically that would tell me that when it was approved, the information the FDA acted on, they made a decision that it was safe and effective, the drug has been out for a while, that doesn't necessarily hold true today.

Q. Okay. If I showed you a letter that says it's been deemed safe and effective, Sulindac, by the FDA in relation to its warning, wouldn't that be proof that its warning is perfectly efficacious and perfectly adequate?

A. No, because again, the warning is going to be based upon the safety information that's going to be

* * *

Q. Okay. Have you reviewed data or information, Dr. Tackett, regarding the types of drugs which at one point were approved as safe and effective where that decision has been changed?

A. There's been several that's occurred over the years.

Q. Okay. Have you reviewed a published list of those drugs and approximately how many are on it?

A. Well, the FDA will publish a list that basically will talk about drugs that are no longer safe and effective, and those are available on the website.

Q. Okay. And have you reviewed Exhibit 1007 in that regard?

A. Yes.

Q. And approximately how many drugs are listed on that FDA publication?

A. I think there's around 63.

Q. Okay. And for all those 63 drugs, does that mean also --

MR. THOMAS: Objection, we're beyond the scope.

MR. JENSEN: It's cited in his report, your Honor.

THE COURT: Yeah, I'll allow it. But stop leading him. Ask him open-ended questions.

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
KAREN BARTLETT, Plaintiff
v.
MUTUAL PHARMACEUTICAL COMPANY, INC.,
Defendant
Civil No. 08-cv-358-JL
August 24, 2010
8:20 a.m.
Day 7 Morning Session

TRANSCRIPT OF TRIAL
BEFORE THE HONORABLE JOSEPH N.
LAPLANTE AND A JURY

* * *

Q. Okay. Does scarring like this, in your experience, resolve, does it go away?

A. No. Scarring is permanent. Once the skin is, that outer seven layers of epidermis is replaced by fibrotic tissue, that does not go away by itself. Does not change.

Q. I kind of asked the question but have you evaluated and thought about whether this scarring will be permanent, last Karen for the rest of the remainder of her life?

A. Yes, and I did relay that to Ms. Bartlett.

Q. Okay. What's your conclusion in that regard?

A. That it is permanent.

Q. Okay. What is your conclusion, if you have one, as to the likelihood of Karen ever being able to have intimate relations in her life?

A. I would say that it's not going to change. It's impossible. It hasn't changed over the year since I've seen her. I don't expect it to change at all.

Q. Thank you, doctor. What if anything else, I don't want to cut you off, do you find was relevant, or have we covered it?

A. I think that's it.

Q. Great. Do you commonly, Dr. Pliskow, or not, provide referrals for your patients to psychologists or

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
KAREN L. BARTLETT, Plaintiff

v.

MUTUAL PHARMACEUTICAL COMPANY, INC., Defendant

Civil No. 08-cv-358-JL

August 24, 2010

1:00 p.m.

Day 7 Afternoon Session

TRANSCRIPT OF TRIAL BEFORE THE HONORABLE JOSEPH N. LAPLANTE AND A JURY

* * *

Q. What type of information or data did they have to base the withdrawal of Bextra on in relation to SJS and TEN?

A. Just individual cases, individual reports.

Q. And do you teach epidemiology?

A. Yes.

Q. What is a case controlled study?

A. A case controlled study is a very well-accepted epidemiologic study in which you have a control population and you have a population at risk. A population at risk with case control studies is the population expressing the disease. You match the population, who's got the disease, with controls the best you possibly can and then track back through the data to try to see what factors affected the people getting the disease.

Q. In a perfect world would you always want a case control study before you decide to take a drug off the market or not?

A. Yes.

Q. Was there any case control information like you just described, Dr. Salisbury, that the FDA relied on in deciding to take Bextra off the market?

A. No. They recognized that this was something

* * *

[T]here were nine deaths, but most of the cases of Stevens-Johnson's/TENs that occurred with Bextra were SJS cases. There were about 116 --

Q. Stop there. And did you look into other NSAIDs that had been withdrawn from the market also other than Bextra?

A. Yes, they are in my report.

Q. Let me ask you this. How many of the NSAIDs that have been taken off the market through the time Bextra was taken off the market, Dr. Salisbury, ever had the benefit of having case control information, which you just described to us, as a basis for taking it off the market?

A. None.

Q. How can that be, Dr. Salisbury? You said in a perfect world we'd want such data. How were these decisions made? Tell us.

A. It's very easy. This is a very rare disease. It's a very rare disease. There's one to two per million. And you're asking the FDA -- if you really believe that, it flies in the face of who we are as an American people; i.e., what you're saying is -- what you would be saying

is, well, we have evidence that this is a bad drug and should be taken off the market, but we don't have case control studies.

Well, that takes a lot of time. It takes a lot of patients to have statistical significance. The FDA is the watch dog. It's supposed to protect us.

Q. Have you ever heard anyone assert that the FDA ever had this type of case control data before it took any of these other NSAIDs off the market?

A. No.

Q. Tell us about WHO data that you just mentioned and the deaths in relation to Bextra and Sulindac.

A. Would you repeat the question, please.

Q. Yes. Tell us -- what is the WHO you just referenced?

A. That's the World Health Organization.

Q. Tell us about this World Health Organization data you reviewed in relation to that to the deaths. You just gave us nine for Bextra and 38 for Sulindac.

A. Yes, sir. We looked at it from 11/30/77 until 1997 and we found with Sulindac there were 38 deaths. 32 in the United States and six abroad.

Q. You also mentioned you reviewed AERS data for SJS and TEN? What's AERS mean, please.

A. Well, that's the FDA Adverse Event Reporting System, and I'm embarrassed to tell you that there are problems with that because of duplication. This is a well-known criticism.

* * *

THE COURT: No, that's fine.

THE WITNESS: Thank you, your Honor.

A. Could we go back please starting with hierarchy so I don't get confused or confuse anyone else. I think that there should be mortality data in the warning. I think that would make the warning very efficacious.

Q. Okay. Let's start there then.

A. That's because that's the most important thing. That's what people want to know.

Q. What is mortality data?

A. Mortality data is am I going to be at risk of dying if I take this drug? What's the chance -- any drug, what's the chance?

Q. Is there mortality data for SJS and TEN?

A. Absolutely.

Q. What is it?

A. Between 30 and 80 percent. At my hands TENs cases put side by side with burn cases of the same size, I do much worse -- it's a much more virulent process than a pure burn injury. So if I have somebody with a 70 percent third-degree burn in my burn center, I have a 50 percent chance of saving his or her life. So we've come a long way.

* * *

Q. What kind of drug is aspirin?

A. It's salicylic acid. It's an NSAID.

Q. Are there different types of NSAIDs?

A. Yes, there are different classifications.

Q. And is aspirin an NSAID just as much as Sulindac is an NSAID?

A. Yes, that's correct.

Q. Do you know of any evidence at all that aspirin causes SJS and TEN?

A. No.

Q. Do you know of any evidence at all that aspirin is associated with SJS and TEN?

A. No. The literature is pretty clear on this.

Q. Have you heard anyone assert in relation to this case that aspirin causes SJS and TEN?

A. No, sir.

Q. From an SJS/TEN perspective, is aspirin a safer NSAID than the other NSAID Sulindac?

A. Absolutely.

Q. And can aspirin be given in higher doses in the hospital or other places that you might read on the bottle that you take from the store?

A. Yes.

Q. Is aspirin -- do you have an opinion as to whether or not aspirin taken in the proper dose can be equally effective as Sulindac?

A. Yes, I do.

Q. What is your opinion?

A. I believe it can be.

Q. What about the proposition -- forget the proposition. What relevance, if any, does the fact that -- if you're going to a doctor like an orthopedic surgeon, you don't expect him to tell you to take two aspirin and call me in the morning. Is aspirin really just as effective as a prescription drug?

MR. THOMAS: Objection.

THE COURT: Basis?

MR. THOMAS: Leading, very.

THE COURT: Yes. Try it a different way.

Q. Is aspirin really just as effective a drug as something you can get from a prescription?

A. Once again, you go back to the makeup of the person who's taking the medication. By that I mean some people are very sensitive to pain and others aren't, and also what the indications are. If what you are taking, the pain medicine for it, if you just had your hip replaced, I think you would need something a little stronger than aspirin. Depends. And this gets back to indications and gets back to risk/benefit.

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
KAREN BARTLETT, Plaintiff
v.
MUTUAL PHARMACEUTICAL COMPANY, INC.,
Defendant
Civil No. 08-cv-358-JL
August 25, 2010
1:30 p.m.
Day 8 - Afternoon Session

TRANSCRIPT OF TRIAL
BEFORE THE HONORABLE JOSEPH N. LAPLANTE AND A JURY

* * *

[W]e will proceed with the direct examination of Dr. Salisbury. Doctor, you're still under oath.

THE WITNESS: Yes, sir.

THE COURT: Please proceed.

MR. JENSEN: Thank you, your Honor.

ROGER SALISBURY having been previously sworn, testified as follows:

REDIRECT EXAMINATION cont'd

BY MR. JENSEN:

Q. Dr. Salisbury, when we broke we were discussing the statement of the board, the highest adjusted reporting rate of SJS and TEN or NSAIDS is that of Sulindac. Do you recall that, sir?

A. Yes, I do.

Q. Do you know whether the FDA had that information, Dr. Salisbury?

A. They did not.

Q. How do you know that?

A. I know that because Dr. Stern stated that in his deposition.

Q. And who was the person who created or attained that data, sir?

A. Dr. Stern.

Q. Who is Dr. Stern?

A. Dr. Stern is a professor at Harvard of dermatology who has published for the last 30 years on the statistics and problems with scarring.

Q. Do you know whether or not he's associated with this case?

THE COURT: Sustained. Unless you don't object.

MR. THOMAS: No, I was on my feet.

THE COURT: Sustained.

Q. Is this important to your opinions that the FDA did not have this information?

A. Absolutely.

Q. Okay. When Mr. Thomas discussed your filing with the FDA, do you recall that, sir?

A. Um --

Q. Do you recall his questions about that?

A. Yes.

Q. Okay.

A. You mean the Citizen's Petition?

Q. Yes, sir. When that was filed, Dr. Salisbury, by you and others, did you have this information that Sulindac had the highest adjusted reporting rate of SJS and TEN of NSAIDS?

A. No, I didn't.

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
KAREN BARTLETT, Plaintiff
v.
MUTUAL PHARMACEUTICAL COMPANY, INC.,
Defendant
Civil No. 08-cv-358-JL
August 26, 2010
8:45 a.m.
Day 9 Morning Session

TRANSCRIPT OF TRIAL BEFORE THE HONORABLE JOSEPH N. LAPLANTE AND A JURY

* * *

A. Because of the TENs being the underlying cause of all the surgeries, the surgical care is much more complicated than a typical patient. If a typical patient after a corneal operation needs a visit let's say in the first 90 days three or four times, you could divide those 90 days up by every other day or every third day in a patient with TENs and maybe have to see the patient 30 times in 90 days or 45 times. So it's a completely different scenario.

So I think I answered your question.

Q. You did. Previously when you were discussing standard cornea transplants standing before the jury, you talked about the length of time a standard cornea transplant works. Do you recall that, sir?

A. Yes.

Q. Let me now show the jury 1951 ID for the record. We're now looking at the actual Boston Keratoprosthesis that you discussed.

MR. COSGROVE: Objection, leading.

THE COURT: Sustained.

Q. What are we looking at here on the screen, Dr. Chodosh?

A. These are two photographs, slightly different angles, of a design of the Boston Keratoprosthesis. The device on the left is the Boston Keratoprosthesis Type 1, and that's what was used in Karen, and it's used in patients who have an eyelid that opens and closes and have a reasonable amount of tears, reasonable enough so that you think the surface will remain wet. And the version on the right is for those that have literally no tears or are so scarred that the eyelid literally won't move or close, and in that case we do the same surgery, but we remove all the mucous membrane and fuse the eyelids closed around the anterior projection of that.

So the patient has her eyelid sewn shut except for a tiny three-millimeter plastic window. That's so-called Type 2 Keratoprosthesis, but Ms. Bartlett's had only the Type 1 Keratoprosthesis.

Q. What is this we're looking at, Dr. Chodosh?

A. Those are two designs. On the left, the threaded design, which we no longer use, and on the right the so-called snapping design which is showing you component parts of the Type 1 Keratoprosthesis. Where you will see, it says front plate lens, it's like a nut and bolt design, but that contains the bolt, if you will, is the optical lens through which Karen sees in her left eye, and that is designed to have a refractive component so it's like a lens in your eyeglasses, so it's curved to fit the eye so the patient could best see.

The middle piece is the back plate. So this is constructed around a corneal transplant. You take a -- may I?

Q. Sure.

A. You take a donor cornea and you trephine or punch a three-millimeter hole in the center and then the --

Q. A trephine is what?

A. It's this cookie-cutter blade, and that makes a round hole.

Q. A circular blade?

A. Yes. And you literally slip that front plate lens that's in the picture at the top part on the right through that hole, and then the back plate, which is in the middle on the right which has the holes in it, you slip that on the bottom of that bolt, and in this case it sort of snaps in. There's a groove, and if you give it a little push, it snaps in place creating a sort of sandwich between the front plate and the top and the cornea. And then at the bottom it says locking ring, and that's a little titanium ring with a little slit in it so that it can expand, and that slides up over that stem of that bolt, if you will, and expands, and then it finds its little groove, and that C shape narrows again and it holds the whole thing in place and then that

* * *

A. Unfortunately in Karen's case the gluing never really worked. The underlying condition was such that -- there just wasn't enough healing. There are two forces. There's a healing force and a melting force, and in Karen the melting force seems to win. And so gluing and allowing the body to heal itself never worked,

though she had it a number of times. And when I got there in July and started working, Karen became my patient, and she was already in that state of having an area of melting.

Q. Let me address this July entry. July 30, '08, says ER. Does that stand for emergency room?

A. Yes.

Q. What happened in the emergency room that day?

A. Well, Karen came in and was seen to have an area of melting.

Q. And when you describe melting, can you explain what that means, if anything, in relation to the eyeball?

A. It's literally an ulceration. If you think about an ulcerative stomach it's an excavation of the tissue. It's like a backhoe came in and dug away the tissue and it's gone. So you have a round surface and someone took a divot out of it. If you were playing golf and caught a lot of grass, you'd have a hole in the ground. That's what an area of melting or ulceration looks like on the eye.

Q. You said like a backhoe coming in and doing excavation?

MR. COSGROVE: Objection, leading.

THE COURT: Sustained.

Q. Why did you describe it in the manner you did?

A. It's hard for people to understand melting and ulceration. I tried to give them a visual image to understand. In this case it's not that someone came in with a backhoe. It's that the enzymes that are present in these chronically inflamed tear film eyelids are

enzymes that are also present in remodeling and healing, but the balance is lost. So if you heal a wound, part of the healing process is removal of blood, removal of scab, removal of scar, and that requires enzymes that actually dissolve tissue. But concurrent with that are other enzymes that build tissue. In Karen's case the balance is shot. It's gone. So that you have the enzymes that are dissolving tissue, but the enzymes that will build the tissue back are not working, and it's difficult to understand actually. If we fully understood it, we might have a solution to her problem.

But this is a normal occurrence in Toxic Epidermal Necrolysis, Stevens-Johnson eye, to have this imbalance of enzymes which lead to melting.

You think about a stick of butter melting, that's literally what it's like.

Q. Let's get up to your first operation and go through these pictures that you asked me to show the jury. Let's take this one first in April 2008, which is the date there and tell us which of these images we should focus on.

A. The one in the center is fine.

Q. What does it show us? Is this Karen's eye?

A. Yes, this is Karen's left eye. Refresh my memory on the date.

Q. April 2008, sir.

A. So this is before I was caring for Karen, but this is at a relatively good phase after her second surgery, and in this case the back plate is the metal, the titanium, which has been one of the more recent advances in the science of the device. It engenders less

of an immune response, less inflammation, than the plastic.

And here things are looking for Karen good. The tissue's all intact. It's inflamed, but that's her baseline. But the tissue is there. It's supporting the device and affording at least a clear window to see through.

* * *

[S]he came back in the region of 20/60, 20/80. That's corrected. And I don't know if you understand what 20/80 means, but if I'm 20/20 and one of you is 20/80, I can see at 80 feet what you have to be at 20 feet away to see. So that means you can only see as fourth as far. So the second surgery her vision came back -- should I be talking?

MR. JENSEN: May I approach?

THE COURT: You may.

MR. JENSEN: Thank you.

Q. Let me ask you because you started talking about visual acuity. You mentioned legal blindness before. Tell us what that is.

A. Yes. Legal blindness is equal to or less than 20/200 vision in your better eye, or a visual field smaller than 10 degrees, but that's not really relevant for Karen. It's one or the other.

Q. Can I write equal to or greater than 20/200 in your better eye?

A. That line would be the other way. So it's vision less than -- and then a line under it.

Q. Okay.

A. Yeah. So that's the sign for less than or equal to, visual acuity less than or equal to.

Q. And what's 20/400?

A. 20/400 is worse that 20/200. So 20/400 vision would mean that -- I could see 400 feet away where a person with 20/400 vision has to be 20 feet away to see. So when you think of yourself on a highway, you are looking at signs, for example, as they approach. If I have a 20/400 person in my car and I can see a sign, the lettering is big enough to see at 400 feet, they would have to be 20 feet away to see the same sign and resolve it and know what it read.

Q. How does 20/400 relate to 20/200?

A. It's worse than 20/200.

Q. How much worse?

A. By half. So the person who is 20/200 can see twice as far as the person who is 20/400.

Q. Generally what, if anything, do doctors do to record visual acuity when it's worse than 20/400?

MR. COSGROVE: Beyond the scope.

MR. JENSEN: He's done this. It's recorded.

THE COURT: It doesn't make any difference.

Q. Has Karen ever had vision worse than 20/400?

A. Yes. She currently does in her right eye.

Q. Give us other visions she's had as they get worse than 20/400.

A. There are ways to determine vision with numbers past 20/400, but they are not commonly done[....]

* * *

Q. Does the letter C appear in your medical records?

A. Yes. That stands for count fingers.

Q. Does the letters HM appear in your medical records?

A. Yes. That stands for hand motion.

Q. Has Karen had both of those visions in her eyes at periods of time that we'll discuss?

A. Yes.

Q. I want to write it down correctly in terms of the big E. Tell me what I should write down here as to whether you can see the big E or not if you are at 20/400.

A. Well, if you can resolve the big E and that's the best you can do, you would write 20/400.

Q. That's the only letter you can see?

A. Yes.

Q. Big E only?

* * *

Attorney Cosgrove's objection -- it isn't that the question is a leading question. It's the method of examination is directing him to documents and having him comment. That's also leading. I'm not going to strike the testimony, but ask open-ended questions about topics. Don't pick records out and have him describe it.

Q. What is your assessment of Karen's ability to see at this time, sir?

A. The current time?

Q. Right now in August 2009.

A. That she was legally blind.

Q. What was your assessment -- did you make an assessment as to whether she could see well enough to work, drive, or read?

A. I would like to explain this answer. So reading vision is 20/40, 20/50 vision. That means, again, seeing about half as far as I can, being 20/20. So that's what you need to be able to read.

To pass a driver's test, depending on the state you live in, some states 20/40 in your better eye, some states 20/50, but it's always in that range. No state allows you to drive at 20/200 vision.

Working usually requires driving and reading, usually. There are jobs that people can do who are legally blind if they are trained and have enough comfort so they can get through a workday. That occurs. But it was my impression at that time and remains my impression that Karen is not going to, for any appreciable length of time and certainly not on a long-standing basis, achieve vision necessary to drive or read and therefore to work using her eyes.

Q. And is that assessment reflected in your sentence here where you say: Although we intend to continue to try to improve Ms. Bartlett's vision, the most probable outcome is that she will not ever recover vision sufficient to work or drive or read?

MR. COSGROVE: Objection, leading.

THE COURT: Sustained.

Q. Tell us what was your impression at this time in relation to this exhibit that's in evidence, 531B?

A. I wrote that sentence because sometimes when you write a letter that's used, for instance, at a

workplace or disability, the next question is, is this a temporary or permanent condition? That's on every disability form I've ever filled out. I don't have any specific knowledge of the disability form that Karen would have in the state she lives in, but on every disability form I've ever seen and working in multiple states, they ask for the best level of vision that the

* * *

[B]ut I don't really believe in my heart that we're going to get much beyond that.

Now, we still have the right eye, and the right eye I think that with a Keratoprosthesis her vision could be temporarily restored to some reasonable level, but based on everything I know about Stevens-Johnson/TENs, and everything I know about Karen even more importantly, I think that will also be a temporary condition. Likely she will have multiple surgeries in her right eye, and we're going to put off that as long as I can to prolong her lifetime of seeing something.

Q. Let me ask if I might, Dr. Chodosh. So she's had 12 surgeries so far; correct?

A. I believe that's correct.

MR. COSGROVE: Objection.

THE COURT: Sustained.

Q. How many surgeries has she had so far?

A. Twelve.

Q. Have you assessed how many surgeries you think she will likely need in the future?

A. I think one could expect more surgeries on the left eye. The first Keratoprosthesis she had lasted I think a year and a half, almost two years, and then it

seems like the trend is that they are lasting less and less. Her eye with each surgery there is damage. As a surgeon you know you are trying to restore her vision, but every time you operate you are distorting the normal tissue and so there is damage literally to the eye with each surgery.

So I would expect that we may have to make more Keratoprostheses in this left eye, but I also expect at some point she'll have a retinal detachment or her glaucoma will be out of control. Retinal detachments occur in a third or approaching 50 percent of patients with this condition who have Keratoprostheses. So the expectation is that there is a reasonable likelihood that she will have a detachment. Some of them can be repaired, but patients almost never regain their vision past light perception or count fingers vision.

So I'm expecting several more surgeries in her left eye hopefully that retain vision along the way. In her right eye I think one could predict a very similar course of action. Again, we're trying to understand Karen specifically and what's unique about her so that we could have a better course with her right eye, but there is certain things that I can do and certain things that are left to providence, and I think if I'm honest about it, I think we're likely to have a similar course in her right eye.

We're going to try to make it simpler for her and have more success obviously. We're trying very hard through a variety of means to understand why the melting occurs in Stevens-Johnson and what the mechanisms are and looking for new medications that might alter that, but things being likely, I think we can expect a similar course for the right eye.

Q. When you say we can likely expect a similar course for the right eye, that means how many surgeries will likely result in her right eye in the future?

A. Well, similar would be 10 to 15 or 20 surgeries. I think that's reasonable.

Q. You also mentioned there will likely be a retinal detachment in her left eye; correct?

MR. COSGROVE: Objection, leading.

THE COURT: He just said that; right? He testified to that already. Overruled.

Q. You also testified there will likely be a retinal detachment of her left eye; correct?

A. I did.

Q. Why do you believe there will likely be a retinal detachment in her left eye?

A. We looked back at patients with autoimmune diseases and --

* * *

Q. In relation to that statement here, NSAID Sulindac caused Stevens-Johnson Syndrome, do you know of anyone at Mass. Eye & Ear with whom you've worked who ever disagreed with that proposition?

A. No, I don't.

Q. Have you discussed that proposition with your colleagues at Mass. Eye & Ear?

A. Not specifically. I mean, she came to us. She was seen first at the Mass. General burn unit, and those are the people that treat this from start to finish, and it was their determination that this was the drug

that caused it. There has never been a suggestion of anything else doing it.

Q. If Karen Bartlett never had TEN, Toxic Epidermal Necrolysis, Dr. Chodosh, would she ever have needed any of the 12 surgeries we've discussed?

A. No.

Q. If Karen Bartlett never had TEN, would she have the likely need for several additional eye surgeries in the future in her left eye?

A. No.

Q. If Karen Bartlett never had TEN, would she likely need the 10, 15, or 20 surgeries you think she will need in her right eye?

A. No.

MR. COSGROVE: Objection, calls for speculation.

THE COURT: Let me read it.

(Pause.)

THE COURT: No, I will overrule it.

Q. Let me ask it again so you remember. If Karen Bartlett never would have had TEN, would she likely have the need for 10, 15, or 20 additional surgeries in her right eye?

A. No.

THE COURT: Can you say that to a reasonable degree of medical certainty?

THE WITNESS: Yes.

THE COURT: Overruled.

Q. And if Karen Bartlett never had TEN, would she have the likely future of retinal detachment and light perception only in both eyes?

A. No.

MR. COSGROVE: Same objection.

THE COURT: Noted.

Q. Your answer, sir?

A. No.

Q. Thank you, sir.

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
KAREN BARTLETT, Plaintiff
v.
MUTUAL PHARMACEUTICAL COMPANY, INC.,
Defendant
Civil No. 08-cv-358-JL
August 26, 2010
1:35 p.m. - Afternoon Session
TRANSCRIPT OF JURY TRIAL
BEFORE THE HONORABLE JOSEPH N. LAPLANTE

* * *

Q. Is it related to the Harvard Medical School or not?

A. It's its own standing entity with a close association to Mass General Hospital and Harvard.

Q. Thank you. It says, "In combination with Shriners Pediatrics Burn Hospital where I contribute significantly to the clinical program. The burn center has the highest survival rate in the world." Is that what it says, Dr. Ryan?

A. Yes.

Q. Was that your belief when you published this in your CV?

A. Yes.

Q. The jury has heard from Dr. John Schultz. Did he play a significant role in making this burn center have the highest burn survival rate in the world?

A. Yes.

Q. Have you dedicated much of your professional career to the best possible care, treatment, assessment and diagnosis of burn patients?

A. Yes.

Q. Tell us, how many burn beds are there at the

MR. JUDGE: Objection. Leading.

THE COURT: Sustained.

Q. What, if anything, did you do in your practice as relates to Karen Bartlett to try to figure out what caused the SJS and TEN?

A. Mostly it's a careful history and trying to go through if there were any new medications given in the time period of the few months prior to the start of the rash.

Q. In 2005, did you assess what was the most likely cause of your patient Karen Bartlett's TEN?

A. I didn't personally. The team did.

Q. What was the team's conclusion?

A. That the TENs was caused by the nonsteroidal anti-inflammatory drug.

Q. And which drug was that?

A. Sulindac.

Q. And you said this was the team that discussed this. Would that have included these team members?

A. Yes. Plus other people, as well.

Q. Would it have included Dr. John Schultz, who the jury heard from?

A. Yes.

* * *

Q. Dr. Ryan, what, if anything, is a hypersensitivity reaction in relation to SJS and TEN?

A. What do you mean?

* * *

Q. Have you ever heard of a hypersensitivity reaction, Dr. Ryan?

A. Yes.

Q. What does it mean?

A. It's a very nonspecific term.

* * *

Q. In relation to Karen Bartlett, why is hypersensitivity a nonspecific term?

MR. JUDGE: Objection, your Honor.

THE COURT: Overruled.

A. Well, I think that hypersensitivity reactions – it's a very general term. It could mean anything. It could mean syncope. It could mean a rash. It could mean a thrombosis, a liver problem. It's just a reaction to a drug.

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
KAREN L. BARTLETT, Plaintiff

v.

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Defendant

Civil No. 08-cv-358-JL

August 27, 2010

8:20 a.m.

DAY 10 - Morning Session

TRANSCRIPT OF TRIAL
BEFORE THE HONORABLE JOSEPH N.
LAPLANTE AND A JURY

* * *

Q. Did your husband Greg become his patient as well at some point?

A. Yes. And my son and my sister and my brother-in-law, my nephew and his wife.

Q. Is that what they call family physician?

A. It's a family physician, yes.

Q. And were you ever -- have you ever been hospitalized for anything in your life at this point?

A. For more than a day surgery, no.

Q. Did you come to know a doctor named Dr. Ergin?

A. Yes.

Q. How did you come to know him, please?

A. Well, I've had pain in my shoulder and Dr. Lane sent me to -- wanted to send me to an orthopedic surgeon, so he sent me to Dr. Ergin.

Q. Did you go see him?

A. I did.

Q. And did you tell Dr. Ergin what your symptoms were?

A. Yes.

Q. And what did you tell him?

A. Well, I showed him where the point of pain was if I moved my arm. I also had a set of x-rays that Dr. Lane had sent me for, for him to go over, and I basically just told him about where the pain was in my shoulder.

Q. Please describe that pain for us.

A. Well, if I put my arm up or try to put it behind my back I got a really bad pain in my shoulder. If I moved it another way, it was less. But if I was just doing regular everyday things, movements, I didn't have any pain.

Q. And is that what you told Dr. Ergin?

A. I'm assuming because that's how it was.

Q. Okay. Did he discuss how he might treat your shoulder pain?

A. Yes. He said -- he suggested a cortisone injection.

Q. And what was your response to that?

A. Well, I asked him if there was another option.

Q. And what did he say?

A. He said that he could give me home therapy like give me sheets that show me some exercises to do, ice pack, and take -- he prescribed actually Clinoril, and

he said that would reduce the swelling and pain in the shoulder.

Q. And did he -- was it your understanding that he was proposing this shot to you?

A. Yes, that was his first option[.]

* * *

Q. Did you ever go pick up a prescription for Sulindac from Dr. Ergin?

A. Yes.

Q. Okay. And did you first start taking it that day -- hold on. Do you remember what day it was prescribed to you, Ms. Bartlett?

A. Yes. My appointment was December 30th.

Q. Of what year, please?

A. I'm sorry, 2004.

Q. Okay. And did you start taking it that day?

A. I did not.

Q. Why not?

A. I had a colonoscopy scheduled for January 4th, and you're not supposed to take anything seven days before or seven days after, so I delayed taking that because it was within my seven days of when I wasn't supposed to be taking anything.

Q. Did your doctors who did the colonoscopy give you those instructions?

A. Yes.

Q. Okay. And did you comply with those doctor's instructions?

A. Yes.

Q. So when, if at all, did you take your first Sulindac pill?

A. Well, it would have been seven days after my colonoscopy, so it was January 12th.

Q. Okay. Can you see that calendar from where you're sitting, Ms. Bartlett?

A. What calendar?

Q. Okay. And, so did you take -- did you take Sulindac as prescribed starting on January 12th?

A. Yes -- well, that first day I believe I forgot to take the first one, so I actually took my first one that night.

Q. Okay. And January 12th. You can't see that?

A. No, I can't.

Q. Can you see me right now, Mrs. Bartlett?

A. I can see a dark shape right there, but if you talk --

Q. If you didn't know, if my hair was red or blond or brunette, could you tell right now?

A. No.

Q. Okay. Thank you. Okay, so you start taking January 12th; is that right?

A. Yes.

Q. And did you take it every day as prescribed throughout the remainder of January?

A. Yes.

Q. Okay. And how was it prescribed? How many times a day?

A. Supposed to take it twice a day with food. So I would take one with breakfast and one with supper.

Q. Okay. And the jury has heard about a trip to Taiwan Cafe. Do you recall that?

A. Yes.

Q. Okay. And do you recall when that was?

A. January 29th. It was a Saturday.

Q. And January 29th, Saturday, were you still taking Sulindac?

A. Yes.

Q. Okay. And tell us about that Saturday night, please.

A. That Saturday, um, I had made plans with my friends Becky and Linda from church to spend the day in Boston, walk around, have lunch, and we had tickets to go see the Lion King. And Becky loved this little Chinese restaurant in Chinatown that she always went to with her daughter, and like she said, when she was young, so we just went with her because we couldn't decide where else to go, so we went with her to that little Chinese restaurant and we had her order, we just ordered like three or four different items, regular Chinese things, to me, and we just shared what was on the table. And the food is really good. And after, after that we walked over to the opera house to see the matinee of the Lion King.

Q. Was it a good show?

A. Wonderful, wonderful show. I'd go see it again if I could. It was a wonderful production.

Q. What happened next?

A. Well, after the show we just went right home. Linda was driving. So we drove back to her house. Becky just jumped -- she wanted to get home, so she got in her car and left and I went in with Linda into her house, and

we were sitting chatting for awhile because she was going to be going to Salem, her husband was doing the sound for a friend's band at some place in Salem, New Hampshire; and she was going up there. He had their son with him and she was going up there to pick him up and maybe listen to the band for a few minutes and asked me if I wanted to go with her, and I said sure, because I was always game to do things. So, but then my stomach started acting up, so I ended up not going.

Q. Okay. And did you go home and go to bed that night?

A. I did.

Q. Okay. And tell us about Sunday morning, then.

A. Well, Sunday morning -- I had actually had diarrhea Saturday night, and then Sunday morning I still was -- it wasn't as bad, but I ended up not going to church that day. And so I just stayed home and by Sunday night I was fine.

Q. Thought you were over your diarrhea?

A. I was.

Q. Okay. And tell us about Monday, then, please, and do you remember what day Monday was, the date?

A. That would have been January 31st.

Q. Okay. Tell us about Monday, please.

A. Well, I got up and went to work.

Q. Worked the whole day?

A. No. I ended up leaving early because I was starting to not feel well. I don't remember exactly how I wasn't feeling well, but I remember leaving early, and, you know, just told my boss I wasn't feeling good, I was taking the rest of the day off and went home.

Q. What happened the rest of Monday?

A. I don't remember exact details. I must have just stayed home and just relaxed so I could feel better so I could go to work the next day, because I didn't like to miss work.

Q. And was that your intent when you fell asleep that night, to go to work the following day?

A. Yes.

Q. And what happened the next day on Tuesday?

A. Well, I really wasn't feeling well, I guess, Tuesday morning when I got up, so I ended up calling in sick.

Q. And did you take -- did you take Sulindac on Saturday and Sunday and Monday?

A. Yes.

MR. JUDGE: Objection, leading.

A. Oh.

THE COURT: I'll allow that. Let's be careful.

Q. Sure. Now, on Tuesday, what if anything did you take that morning?

A. Tuesday was February 1st. I took my Sulindac that morning.

Q. And after you took your Sulindac that morning, Tuesday, February 1st, did you ever take Sulindac again?

A. No.

Q. At all?

A. No.

Q. Okay. Tell us what happened next, then, on Tuesday morning.

A. Well, I was starting with a fever, and as the day went on my eyes started burning[.]

* * *

Q. And did you request these nurses and therapists to come to your house or were they also assigned by your doctors?

A. I guess one -- somebody from the team, I don't know if it was my physical therapist or whatever from Spaulding Rehab, contacted the VNA from Northeast Rehab and set that up. The visiting nurse came the day I came home to make sure I was all set with everything and gave me the information, the contact number if we needed them at any point, and --

Q. May I, your Honor?

THE COURT: You may.

Q. I'm just going to show the jury, Karen, show them your hospitalizations. Do you remember approximately when you got out of Spaulding Rehab in 2005?

A. I think it was May 19th.

Q. Pretty good memory. Did you have a G tube in through the remainder of 2005?

A. Yes.

Q. Do you remember the day you got out of Spaulding Rehab?

A. Yes.

Q. Okay. Tell us about that.

A. Well, my husband -- well, I got to tell you, my husband, we were so excited that I was getting out, his cousin had a limo service, so he had his cousin come and pick me up in a limo, and my sister and my friend

Linda were in the limo. And so I got to go home in style.

But, yeah, I remember getting home. My neighbors had a, they live next door, they had big signs up and some people from church had come and put balloons on the fence and a sign up saying welcome home Karen. And then, you know, I got home and that day the New England Home Therapies came and delivered the bed, set it up, the hospital bed, and brought the IV pole and everything, and the visiting nurse came and got me all settled in.

Q. Do you remember the surgery to take the G tube out of your stomach?

A. Yes.

Q. Okay. Approximately when was that?

A. That was in April -- it was the middle of April, maybe the second week of April.

Q. Of what year?

A. 2006.

Q. Okay. So a full year after you got out of Spaulding Rehab?

A. Yeah, just about, yeah.

Q. Okay. So tell us about that year being fed through a G tube. Were you able to eat any normal food in that 12-month period?

A. Well, I -- December 28, 2005, I remember the date because it was after Christmas, it was around Christmas I had to have my esophagus dilated because I had gone for speech therapy two or three times a week for over a month outpatient at Northeast Rehab in Salem, New Hampshire, and my muscles had

strengthened, but I still wasn't able to swallow food. So they did want barium swallows and I ended up seeing a thoracic surgeon to have my esophagus dilated.

Q. Can you tell us your understanding of what needed to be done, please.

A. Well, so I could get off the feeding tube because I couldn't -- I couldn't, even though my muscles were strong I couldn't swallow anything enough a day to sustain my weight, so, and I couldn't keep a feeding tube in for the rest of my life, so --

Q. So as of the time you had that surgery you had not had any normal food yet?

A. No. Well, my speech therapist, I'd have like little quarter teaspoons of pudding to see if I could swallow them, but no, my diet was actually the Jevity[.]

* * *

[o]f my things I used to love to eat was lobster dipped in butter, and I couldn't eat it anymore because lobster is really kind of -- not rubbery but it doesn't mush unless you shred it. I basically stuck to soft foods and soups and, you know, anything I could mush. And I always used water because I don't have the saliva production that I used to have because of the scarring tissue and stuff in my mouth, so I drink water like constantly.

Q. After your first surgery through 2009, has it been painful to eat?

A. The first surgery in 2009?

Q. After you had the first surgery through 2009, those four years, has it been painful for you to eat?

A. Oh, it is. It's not all the time, but sometimes things still get stuck like at the top and then through the

center of my chest it like, some things if I don't watch, I have to take really small bites at a time and make sure I chew and mush before I swallow. And the doctor, one of the doctors that had done the procedure in October had told me when you eat, you really shouldn't be like watching TV which I can't do anyway or have a conversation because you really need to concentrate on your chewing, because if you don't, you could aspirate, you know, or it could get stuck or, and I still have a hard time – it kind of scrapes going through the center of my chest down, so I have to have another dilatation done.

Q. Is that scheduled now?

A. Yes. It's going to be September 15th.

Q. Give us an idea, what percent of the time, if you can tell us that you eat, is it painful to eat?

A. It's actually when I try to eat -- when I eat things that aren't soft, so I'd say 70, 70 percent, I'm hard with figuring out percentages.

Q. Have you ever been able to enjoy food since this all happened?

A. I don't because I shy away from things that I used to love to eat. Being Italian, again, I used to love eating a lot of bread and things and bread is just too thick and it's too much of an effort for me. Things that make too much of an effort for me to eat and then have to try to get down, I just stopped eating. So a lot of things that I used to love to eat I don't eat anymore.

And also I used to love like honey buffalo chicken, and I can't have spicy stuff because it burns the cheeks, the sides of my mouth and things like that, so I don't eat spicy foods anymore either like I used to. And so it's not even -- it's not even fun to eat anymore. I'm hoping

after my third dilation it will be better, but, I don't know.

Q. In let's say the first six months of 2006 alone did you go see doctors more than you ever had in your entire life combined before that?

A. Yes.

Q. And has that been true for nearly every month since this all happened that you've seen more doctors on a monthly basis than you ever have in your life before this all happened?

A. Oh, yeah, before all I saw was basically, you know, my physician for yearly physical and of course my normal OB/GYN appointments once a year and things like that but, yeah, Mass. Eye and Ear, I walk in there and everybody is saying hi, you know, hi, Ms. Bartlett, hi Karen, how you doing, because I'm there so much.

THE COURT: Counsel, I'm going to ask you to just be a little bit careful about the leading questions.

Q. Okay. Did you hear Dr. Chodosh talk about an exhibit that showed that you had been to Mass. Eye and Ear over a hundred times between April '05 and August '09?

A. Yes.

Q. Okay. In the last year have you gone to Mass. Eye and Ear more or less or just about the same as those hundred visits in that period of time?

A. I think I averaged probably twice a month unless I have a problem and then it's more.

Q. Can you read that on your screen right now, Karen?

A. Can I read it? No. I can see that there is something there, but I can't see it, no. I can't.

Q. What's your best estimate of how many times you've been to Mass. Eye and Ear in the last 12 months?

A. Gosh, I had surgery in January -- I'd say between 25, 30, around 25 or 30 times maybe.

Q. Two or three times a month on average I suppose?

A. Yeah, on average, because I see -- I have one, two, three -- three doctors that I see there.

THE COURT: Counsel, it's time for the lunch break. Deb. (Jury exited the courtroom.)

MR. JUDGE: Putting things on ELMO when she can't see, I'd like that to stop.

THE COURT: Well, the jury is allowed to see it. Although, you know, really, I mean, you're supposed to use the ELMO when you are using it to help you examine a witness. So it really can't be used to help you examine this witness, can it?

MR. JENSEN: In large part that's correct, your Honor.

THE COURT: So, I mean, let's not milk it. Thanks. (Lunch recess taken.)

CERTIFICATE

I, Sandra L. Bailey, do hereby certify that the foregoing transcript is a true and accurate transcription of the within proceedings, to the best of my knowledge, skill, ability and belief.

Submitted: 1/14/11 /s/ Sandra L. Bailey

SANDRA L. BAILEY, LCR, CM, CRR

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
KAREN L. BARTLETT, Plaintiff
v.
MUTUAL PHARMACEUTICAL COMPANY, INC., Defendant
Civil No. 08-cv-358-JL
August 27, 2010
2:20 p.m.
Day 10 - Afternoon Session

TRANSCRIPT OF TRIAL BEFORE THE HONORABLE JOSEPH N. LAPLANTE AND A JURY

* * *

And I got a letter in the mail from the state saying that I was legally blind and I could apply for the handicapped placard, which I did, and so I'm certified by the State of New Hampshire as legally blind.

Q. Did you and Greg have healthy, intimate marital relations in the eighties, nineties, 2000 and 2005 time period, Ms. Bartlett?

A. Yes.

Q. Were you just as active in that regard in the five years before this all happened as in the prior five years before this all happened?

A. Yes.

Q. Have you attempted to have intimate marital relations since this all happened?

A. We have once.

Q. When was that? What year?

A. I believe it was 2007 because I had a long healing process between the skin and everything else and -- yeah.

Q. And were you able to have marital relations in 2007 when you tried?

A. No. It's very painful, very painful. My first OB-GYN appointment, I will never forget it, after this happened. When he was doing the exam, I told him that I felt like -- I had my son natural childbirth, no drugs or anything, and I told him that's what it felt like was when I had my son being in labor for 15 hours and delivering him. So that's what it feels like.

Q. Based upon what you know and what you feel, do you believe you will ever be able to have intimate relations again?

A. I don't -- I don't think so. It's very painful. It's way too much pain for me.

Q. How did it impact you when you came to this realization?

A. Well, it's quite depressing. You know, it makes me feel like -- sometimes I feel like I'm not a good wife. It's very depressing.

Q. Mrs. Bartlett, do you know who the manufacturer of the Sulindac was that you took?

MR. JUDGE: Objection, foundation, lack of personal knowledge.

THE COURT: Well, he's asking if she knows. There's foundation for that, but I see where you're going and I will pay attention. Do you know?

THE WITNESS: Yes.

Q. How do you know?

* * *

bracelet and he said the water would tarnish it. So I take it off when I get in the shower, but yeah, I wear it all the time.

Q. I'm not sure if it came out clearly. What does your allergy bracelet say on it, if you know?

A. It says allergic to Sulindac and NSAIDs.

Q. Has Stevens-Johnson Syndrome and TENs changed you, Karen?

MR. JUDGE: Objection, leading.

THE COURT: Overruled.

A. Yes, dramatically. It's changed my whole life.

Q. Are you able to address your physical appearance now as you used to?

A. No. I can't see myself, so I don't take as much care I don't think as I used to. I mean, before I'd put a little makeup on or fix my hair. I can't see to fix my hair. I don't know what it looks like. So it's just get in the shower and just let it drip dry. And unfortunately I can't see if I have stains on my clothes, so I have to wait for somebody to say, oh, you've got a stain on your shirt because I can't see it. So I'm not as concerned now as I was before.

Also, how has it changed my life? Well, one of the things was I used to -- at church I used to volunteer in the nursery to take care of the little ones, and now little ones are afraid of me. They shy away from me, I think because of my eyes. Well, I know it's my eyes because my neighbor's grandson at one point said, "What's the matter with your eye? What's wrong with your eyes?" And his little sister was afraid to come near me and stuff, and I love kids, and it really bothers

me that they don't want to come near me. I can't see them.

And, you know, I lost my independence. I used to be -- I used to do things all the time. I constantly had something to do, always going out and doing something besides work, and now I can't do that. I can't just call somebody and say, hey, you want to go somewhere? I'll meet you there, and, you know -- again, I can't see Matt's shows. That was one of my favorite things to do. And actually I was starting to get into the theater, seeing theater, you know, like professional performances, and in 2004 I and a good friend of mine - she was actually my boss at work. We got -- they called them season tickets for the North Shore Music Theater. So we got tickets for four different shows that year, and we enjoyed ourselves so much. We'd go and see the show and have dinner or lunch -- lunch or supper[.]

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
KAREN BARTLETT, Plaintiff

v.

MUTUAL PHARMACEUTICAL COMPANY, INC., Defendant

08-cv-358-JL

August 31, 2010
8:00 a.m.

TRANSCRIPT OF JURY TRIAL

MORNING SESSION

BEFORE THE HONORABLE JOSEPH N. LAPLANTE

* * *

THE COURT: Members of the jury, you heard some testimony, I think it's going to be developed more a little bit, that Dr. Tackett initially gave an opinion as to the number of adverse event reports regarding Sulindac and that he has since modified his opinion about that number. You will hear more about that. That was information that was not disclosed in this case to the other side of the case until recently. You are permitted to consider that late disclosure of that information in assessing Dr. Tackett's credibility as a witness. You may proceed.

MR. JENSEN: Thank you, your Honor.

Q. Did you also assess the number of deaths reported in relation to Sulindac and SJS and TEN?

A. I did.

Q. How many deaths were there?

A. At least 39.

Q. Did that number change?

A. No.

Q. Okay. Is that number -- do you believe that number is valid?

A. I do, and that was confirmed with looking at the other data set.

Q. What other data set is that?

* * *

Supreme Court, U.S.
FILED
JAN 14 2013
OFFICE OF THE CLERK

No. 12-142

IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,

Petitioner,

v.

KAREN L. BARTLETT,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

JOINT APPENDIX, Volume 2

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Shulz, J.T., *et al.*, *A 10-Year Experience With Toxic Epidermal Necrolysis*, Journal of Burn Care & Rehabilitation, excerpt of p. 199 (2000) ..... JA 624

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nonsteroidal anti-inflammatory drugs, excerpts of pp. 1, 10-12, 15-17, 23-25 (Oct. 2001) ..... JA 626

La Grenade, *et al.*, *Comparison of Reporting of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Association with Selective COX-2 Inhibitors*, Drug Safety, experts from pp. 917-18, 922-23 (2005) ..... JA 635

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

KAREN BARTLETT, Plaintiff
v.
MUTUAL PHARMACEUTICAL COMPANY, INC., Defendant
Civil No. 08-cv-358-JL
August 31, 2010
1:15 p.m.
Day 12 Afternoon Session

TRANSCRIPT OF TRIAL BEFORE THE HONORABLE JOSEPH N. LAPLANTE AND JURY

* * *

It could tell that physician he may want to choose a different drug with a lower reporting rate. So if he chooses to make a decision, he can tell them to monitor it closely or he can choose to pick a different drug.

Q. Have you reviewed materials and publications on NSAIDs with reporting rates?

A. Yes.

Q. Have you reviewed such materials relating to SJS and TEN?

A. Yes.

Q. Is reporting rate data in your opinion widely accepted as important to assessing a drug's risk/benefit profile?

A. I think so, yes.

Q. Is it widely accepted in assessing a drug's risk/benefit profile for SJS and TEN?

MR. THOMAS: Still leading.

THE COURT: Whoa, whoa. Risk/benefit profile for SJS and TEN?

MR. JENSEN: Yes, your Honor.

THE COURT: No. Risk/benefit profile means all risks and all benefits. That's permissible. The next question shall be -- disregard the question and the answer.

Q. Tell us specifically what materials and publications you reviewed regarding reporting rate information and NSAIDs.

MR. THOMAS: Your Honor, we've already done this.

MR. JENSEN: No, we haven't.

THE COURT: What materials did he review in assessing what?

MR. JENSEN: The risk/benefit profiles of drugs in relation to reporting rate information.

THE COURT: I don't know what that means, so you will have to rephrase.

MR. JENSEN: Sure.

Q. Have you reviewed any materials or publications pertinent to the risk/benefit profile of Sulindac specifically and SJS and TEN?

A. Well, one that we talked about before lunch was the Mockenhaupt paper.

MR. THOMAS: I object.

THE COURT: I'm sorry. It's leading, and I just don't understand it. I don't understand what the question means, so I can't assess it.

Q. What materials have you reviewed pertaining to the importance of reporting rate information in assessing the risk/benefit profile of a drug?

A. There is published literature that have -- for example, the Mockenhaupt paper indicates that -- we talked about it before lunch -- talks about assessment of risk there. We see that there is the -- there is Stern and Bigby I think have talked about it also with regard to that information.

Q. Stern and Bigby is 1115 marked for identification. And what does it have regarding reporting rate information, Doctor?

A. Is that one going to be put up?

Q. Do you recall what it has regarding reporting rate information?

A. It basically gives information and it ranks the NSAIDs according to that information.

MR. JENSEN: Permission to publish, your Honor.

THE COURT: No, he can testify to it. No. But he can testify about it.

Q. Sure. What is your understanding of why it ranks drugs in relation to their reporting rates?

MR. THOMAS: Objection, foundation.

THE COURT: How does he know why he did what they did? Let's focus on his opinions and the basis of his opinions.

Q. Does it provide a basis for your opinions that there's published -- this is in relation to the Stern and Bigby reporting rates.

THE COURT: You are free to refer to it, by the way.

THE WITNESS: Thank you. That's what I was trying to find here.

MR. JENSEN: Do you want a copy?

THE WITNESS: If you have a copy, that would be great.

A. And so this is basically looking at large cutaneous reactions to drugs, and specifically on table one is that there is a rate that's provided and ranks the different types of drugs. So it gives you an assessment with regard to other drugs that may be prescribed as to what you might expect that the TEN would occur with particular drugs.

Q. Who are the authors of that?

A. This was Bigby and Stern.

Q. Who's Stern?

A. Dr. Stern is a defense expert.

Q. And have you reviewed --

THE COURT: Wait a minute. We talked about that. Disregard the last question and the last answer. It's stricken from the record.

Q. In relation to the qualifications of these authors, who are they?

A. These individuals are all MDs.

Q. And where are they from?

A. Department of Dermatology, Beth Israel,

Boston, Mass.

Q. Do you understand that to be a Harvard teaching hospital?

A. Correct.

Q. Have you reviewed any other publications on this topic of reporting rates?

A. There is also a paper by Dr. Stern in the Journal of American Medical Association.

Q. Tell us about it.

A. Let me get that one. I think it's Exhibit 1247, if you have a copy of it.

Q. I do.

A. And again, this is looking at reports to a specially based spontaneous reporting adverse reaction database, and these particular reports were evaluated by dermatologists going into this. And so specifically on table two, it gives a ratio of reactions, again, a ranking of these drugs, which include Sulindac.

THE COURT: Are you exploring that area of No. 13 on your list here, the bottom of the second page? Is that what you are getting into now?

MR. JENSEN: It relates to that, your Honor. But it also relates to whether this information is important or not to assess risk for a specific drug.

THE COURT: Sure, in a general sense. I'm just cautioning you about -- you highlighted for me the potentially confusing term there, and let's not use it, and if anything you wanted to show the jury uses it, don't show it.

MR. JENSEN: Yes, your Honor.

Q. And so we've got three so far. When was this Journal of American Medical Association article published, sir?

A. This was published actually in 1984.

Q. And the Bigby-Stern, you still have that in front of you. When was this published?

A. I believe it was about the same time. It was actually 1989.

Q. And the Mockenhaupt we talked about, '03.

A. 2003.

Q. So we've got three so far. Any other publications that are relevant to reporting rate information in assessing a drug's risk/benefit profiles?

A. I'm sorry, there is another article by Roujeau that was published in 1990. That's Exhibit 112 I think it is.

Q. Do you have a copy handy, Doctor?

A. I need a copy. I did not bring a copy.

Q. Where was it published, sir?

A. This- was published in the Archives of Dermatology. As I said, published in 1990.

Q. How does it relate to this topic?

A. Again, it's coming in to showing a ranking of these drugs with regard to their potential for causing SJS and TEN.

Q. And it has reporting rates in it?

A. Correct.

THE COURT: A potential for causing? No. You know that that's not permissible testimony, neither disclosed nor reliable.

Q. Does it have reporting rate information in it?

A. Yes, it does.

Q. Is it a peer-reviewed published literature?

A. With reporting rate information.

Q. And does it list various drugs and their respective reporting rates for SJS and TEN?

A. It does. And that includes non-steroidals, anti-bacterials, anti-convulsants, and other analgesics.

Q. Having talked about four publications so far, why is this relative to assessing a drug's risk/benefit profile?

A. Again, it is providing information to the prescriber as to where this drug stands so that if there's a multitude of drugs out there, that prescriber can make the best choice for choosing a drug with the least risk for that particular patient.

Q. Have you reviewed any other materials in this regard?

A. I have reviewed also some documents with regard to the -- Dr. Stern's report, which we talked about before lunch I believe.

Q. Does it have reporting rate information in it?

A. It does.

Q. And did you review any other materials with reporting rate information in it?

A. The Bextra Health Canada.

Q. And what is that document, please?

A. That's basically a document that Pfizer provided to --

MR. THOMAS: Objection, your Honor.

THE COURT: The ruling isn't that he can't mention it.

MR. THOMAS: Yes. The topic is beyond the scope. This is not an issue that he's addressed.

MR. JENSEN: It's within the topic that we just discussed on my list.

THE COURT: I can't read your minds, so I guess we have to approach.

AT SIDEBAR

THE COURT: What are you trying to establish? What are you having him testify about? What are you trying to establish?

MR. JENSEN: That reporting rate information is frequently published and relied on information for assessing a drug's risk/benefit profile.

THE COURT: I think that makes sense. Reporting rate information is relevant to making a risk/benefit profile assessment. I think we need to make sure the jury doesn't confuse risk/benefit profile with risk of causing SJS/TEN.

MR. JENSEN: He gave a nonresponsive answer and quickly informed the jury that they haven't.

THE COURT: You will probably have to do something a little bit more, but that's fine. What's your objection?

MR. THOMAS: He's testified to that. Now he's asking about reporting rate information and Health Canada which is not any disclosed opinion anywhere. This is an unrelated --

THE COURT: No, but he did disclose that he replied on the Health Canada report in his opinions.

MR. THOMAS: Not for that basis. He only relies upon it for one single fact, and that single fact is the

number of cases that there were for Bextra. It's not for comparisons of NSAIDs, not for reporting rates, not for anything.

MR. JENSEN: That goes back to the defense's assertion that you need to put the entire document within your report to be able to rely on it. Obviously he's done a risk/benefit analysis of Bextra and Health Canada. It's part of the risk/benefit analysis of Bextra, and they rely on reporting rate information in that document.

MR. THOMAS: It's not in here.

THE COURT: He can say that much. What are you afraid he's going to have him say?

MR. THOMAS: Well, he didn't rely upon Health Canada for anything at all.

THE COURT: What are you afraid he's going to say?

MR. THOMAS: He started to ask him about risk/benefit information that is in the Health Canada document.

THE COURT: Risk benefit or reporting rate?

MR. THOMAS: That's not in here either. I'm just asking that he be restricted to -- he didn't do anything other than cite it as a basis for saying how many cases there were. So when he tries to use that document on risk/benefit issues, I mean, it's just improper. The witness has already testified about it. He's already testified about numerous sources. He already gave the answer. Counsel raised Health Canada, not the witness, and he's trying to create -- he's trying to drive things through the witness that are not part of his own opinions, and they are also not disclosed.

MR. JENSEN: I haven't given him any literature. He's already gone through four pieces of literature. He came up with the literature and he said why it was relevant to this issue, which is an allowable issue.

THE COURT: I guess I have to take it question by question, but I don't know how either of you expect me to be able to assess whether every slight variation has been disclosed or not. It's impossible to do at the bench on the fly.

MR. THOMAS: I understand the difficulty, your Honor, but I'm also in a difficult spot. I'm able to locate in here because I have a searchable copy of his transcript. I mean, he gave the opinion. Counsel's now interjecting Health Canada.

THE COURT: I will have to take it question by question. When you say interjecting it, he's relied on it.

MR. THOMAS: Not on these kinds of issues at all.

THE COURT: I don't know how you can really say that. It may be true what you're saying, but it's impossible to discern. Unless you went at his deposition through everything he had and ask him for each one what the basis was, and you can exclude it by showing me something in the record, I don't know how I can make that determination.

MR. THOMAS: Well, I can show the Court -- for example, paragraph 135 is where he has the Health Canada reference, and that Health Canada reference only is support for his 186th case.

THE COURT: I don't take quite as restrictive a view as you do on that. At the same time, that doesn't mean you can lead him through things, Attorney Jensen, and just dump it in front of the jury. All I can

do is take it question by question. I don't know how I can do it any better for you.

IN OPEN COURT

Q. How is the Health Canada document you mentioned relevant to the question, Dr. Tackett?

THE COURT: No, you can't answer that question. Try again.

Q. Please tell us what, if any, other information and materials you reviewed that pertain to the question of whether or not reporting rate information is relevant to assessing a drug's risk/benefit profile.

A. Two other documents I've used is -- referred to, is basically the Health Canada, which is assessing risk using reporting rate information, and that was specifically associated with Bextra, and then also I've looked at the FDA decision memo that has reporting rates in it which we referred to as Exhibit 905.

Q. And that also pertains to Bextra?

A. Correct.

Q. Now, we have eight documents. Have you reviewed any other?

THE COURT: What was that? Counsel's count of documents is not evidence. Questions are not evidence. Statements by counsel are not evidence. Proceed.

Q. Any other literature beyond what you've already mentioned that pertain to the question of reporting rates and assessing the risk/benefit profile of the drug?

A. Yes. And then the other study would be the -- I think it's the Le Grand study which was from the FDA that evaluated the SJS and TEN and Bextra.

Q. Any other documents that you reviewed pertinent to this question?

A. With regard to SJS and TEN?

Q. Or otherwise reporting rates and risk/benefit profile of a drug?

A. There is a document in which Provigil was evaluated.

Q. How was that done?

A. Basically by looking at reporting rates, they made a decision as to which population may or may not get the drug.

Q. And what conclusion was reached?

A. That based upon that, they restricted the risk or restricted the use to children could not get the drug.

Q. Did they have any other type of information other than reporting rate information in making that conclusion?

MR. THOMAS: Objection with regard to foundation.

THE COURT: Try to lay a foundation for it and see if you can get it in that way.

MR. JENSEN: Sure.

Q. Was there reporting rate information available that resulted, as you told us, in limiting the use preventing children from getting it?

A. Yes.

Q. Have you assessed what, if any, other information was available to prevent children from getting that drug, Provigil?

A. That was pretty much it.

Q. In other words, there was no other type of data?

A. Correct.

Q. Approximately how many cases or reports of SJS or TEN were there in relation to Provigil that prevented all children from getting it?

A. There was just a handful of cases. I think there were maybe four or five of just SJS.

Q. How is that relevant at all to your analysis of Sulindac?

A. Well, here you have a drug that there's a limit to who can get the drug completely. But there are just a handful of cases versus there are several other cases reported just in the literature and other places with Sulindac and this drug is still on the market.

Q. Did they assess the reporting rate of a much lesser disease than TEN, rashes with Provigil?

A. Yes. Well, SJS. They didn't have TEN in any Provigil cases that I'm aware of.

Q. Did they assess incidence rate of rashes?

A. Yes.

Q. What's the incidence rate of just rashes with Sulindac?

THE COURT: Incidence rate of rashes?

MR. JENSEN: Yes.

THE COURT: Don't answer that.

Q. I'm sorry, what's the reporting rate of rashes with Sulindac?

A. Probably around 3 to 9 percent based on the literature.

Q. That's in published literature?

A. Correct.

Q. Do you have an opinion, Dr. Tackett, or different than what you used before, as to whether or not Sulindac's 2004 label in effect when Karen Bartlett was prescribed the drug was misleading?

A. Yes.

Q. What is that opinion?

A. I believe it was because it didn't include many of the side effects or events that she experienced.

* * *

Q. Give us a list of things that you considered in reaching the conclusion that Sulindac risks exceeded its benefits, please.

A. Has a long half-life. Longer half-life drugs have a higher risk -- NSAIDs have a higher risk for producing SJS and TEN.

Q. What else did you consider?

A. There is medical literature which demonstrates case reports, including rechallenges.

MR. THOMAS: Objection.

THE COURT: Overruled.

Q. Positive rechallenges?

A. Positive rechallenges in the medical literature.

Q. First one I wrote down, long half-life, higher risk of SJS and TEN.

A. Right.

Q. Second one I wrote down, positive rechallenges. Have I got that right?

A. Correct, um-hum. Same thing in the medical literature. The issue that it was not recommended as a first --

THE COURT: Wait a minute. The opinion that the doctor's given is that the drugs with a longer half-life in general that cause SJS and TEN pose a higher risk of SJS and TEN.

MR. JENSEN: Yes, your Honor.

THE COURT: He has not given the opinion that Sulindac poses a higher risk of SJS and TEN than any other drug. We're clear on that; right? You have the word "Sulindac" written on top, and he's giving his opinion right now as to whether the risks outweigh the benefits of Sulindac. If we're going to write on the board, let's be clear about what we're writing and write a comprehensive statement that covers the breadth of the opinion.

Q. What else did you consider in relationship to Sulindac's risk/benefit profiles?

A. The higher reporting rate.

Q. Is that what you mentioned and described as the highest adjusted reporting rate?

A. Correct.

THE COURT: Do you want me to swear you in and put you on the witness stand? If that's what you want? If that's what you want to do, I guess we can do that. Until that happens, please stop testifying.

MR. JENSEN: Yes, your Honor.

Q. Where'd you get that information from, Dr. Tackett?

A. That came from the Stern manuscript or the Stern report.

Q. What else did you rely on?

A. There are safer medications available.

Q. And what are they?

A. That would include aspirin, Tylenol.

Q. And how do they compare from an efficacy standpoint?

A. It's my opinion they are equally efficacious.

Q. What else did you consider?

A. That basically we have -- in addition to the medical literature, we have some case control data which say that ascetic acid group of NSAIDs have a high reporting rate.

Q. And what group of NSAIDs is Sulindac in?

A. It's acetic acid.

Q. What else did you consider?

A. That Sulindac had worse liver problems.

MR. THOMAS: Objection, your Honor.

THE COURT: Undisclosed?

MR. THOMAS: Absolutely.

THE COURT: Counsel, before you keep writing --

MR. JENSEN: I didn't write anything on that.

THE COURT: It's an undisclosed opinion as far as you're concerned? He hasn't said it yet today.

MR. JENSEN: As far as I'm concerned it is in relation to -- yes. But I'd be happy to move on and address it at sidebar.

THE COURT: Yeah, move on.

Q. What else did you consider, Dr. Tackett?

A. Also there's other drugs that have been pulled off the market.

Q. Okay. What are they?

A. That includes Bextra.

Q. What else?

A. Other NSAIDs like the Isoxicam.

Q. Why are they relevant?

A. Those are NSAIDs.

Q. Isoxicam was pulled off the market in relation to approximately how many reports of SJS and TEN?

A. I think that was around 12 or 13.

Q. What we just discussed, Provigil, is that one of the things you considered?

A. Provigil, basically there is a limited indication that was based upon reporting rate of SJS.

Q. And you mentioned it had how many cases of SJS and TEN?

A. I think it was about five, but there were no TEN cases. They were all SJS.

Q. What happened based upon your review as a result of those five reports of SJS and TEN with Provigil?

A. Provigil was restricted so that it can't be used in children.

Q. And does the Mockenhaupt '03 paper, should it appear anywhere on this list?

THE COURT: Please stop leading the witness. The witness can tell you what factors he considered in giving this opinion.

MR. JENSEN: Thank you, your Honor.

Q. What else, if anything, did you consider, Dr. Tackett?

A. The Mockenhaupt paper comes in category number five.

Q. Okay. Does it come up for any other purpose, Dr. Tackett?

A. And Mockenhaupt also would fall into the case of support for the AERS data.

Q. How so, sir?

A. That's where they get the 89 cases.

Q. And that's relevant why?

A. To show the highest number of cases with Sulindac in AERS database.

Q. Highest number of cases of what?

A. Of SJS and TEN.

Q. And how many did you say that was?

A. 89.

Q. Would you take a look at that list and see if it needs to be changed anywhere, Dr. Tackett, and if not, will you sign it, please.

(Pause.)

Q. How many times when an NSAID has come off the market for SJS and TEN was there, based upon your review, only reporting rate information?

A. To my knowledge all of them that have come off are only based on reporting rate.

Q. How many times when an NSAID has come off the market for any reason was there only reporting rate information?

A. I would say it was a hundred percent of the time.

Q. When Provigil was prevented for use in children, was there only reporting rate information?

MR. THOMAS: Your Honor, I'd just object to the ongoing, irrelevant reference to an unrelated drug.

THE COURT: Provigil?

MR. THOMAS: Yes.

MR. JENSEN: It's part of his report. It's disclosed since November of last year.

THE COURT: It is.

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

KAREN BARTLETT, Plaintiff

v.

MUTUAL PHARMACEUTICAL COMPANY, INC., Defendant

08-CV-358-JL

9-1-2010
8:00 a.m.

TRANSCRIPT OF JURY TRIAL

AFTERNOON SESSION

BEFORE THE HONORABLE JOSEPH N. LAPLANTE

* * *

THE COURT: Attorney Jensen, what's next?

MR. JENSEN: Karen Bartlett rests her case, your Honor.

THE COURT: Ladies and gentlemen of the jury, the plaintiff has rested her case. I assume you have a motion under Rule 50; is that true?

MR. THOMAS: Yes, your Honor.

THE COURT: That's preserved, and I'll take it under advisement. We'll take it up later. Are you prepared to present a case?

MR. THOMAS: We are not calling witnesses, your Honor.

THE COURT: All right. The defense has elected not to call any witnesses. That means the evidence part of

this case is over well ahead of schedule than we predicted. So what will happen now, probably tomorrow -- definitely tomorrow is jury instructions and closing arguments, and then you will be given the case to deliberate on. I think the best course now is to excuse the jury until tomorrow morning. Any objection to that, counsel?

MR. THOMAS: No, your Honor.

MR. JENSEN: No, your Honor.

* * *

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett
v.
Mutual Pharmaceutical Company, Inc.
Civil No. 08-cv-358-JL
September 2, 2010
8:45 a.m.
Morning Session

TRANSCRIPT OF JURY TRIAL BEFORE THE HONORABLE JOSEPH N. LAPLANTE

* * *

MR. ROBERSON: In regards to the defect in design section, several objections. First of all, the Court has not included the alternative product instruction. Plaintiffs believe the alternative product instruction is appropriate under New Hampshire law, including the Fortier case.

THE COURT: Right.

MR. ROBERSON: That in the absence of an alternative design, a proper instruction is the alternative product on the market. In the absence of an alternative instruction in regards to an alternative, equally safe, equally effective or safer alternative product is that it creates jury confusion. The jury confusion is created in that the jury is supposed to do a risk/benefit analysis in regards to the product and to society as a whole. In taking into effect society as a whole, the jury has to take into effect what other

products exist in society. A product is not beneficial and effective unless it adds to society as a whole.

For example, the Model T was a beneficial and societally advantageous product in the 1920s. At this point in time, it would be a defective product. It has no seat belts or other items for safety, and there are other products on the market.

So the absence of this instruction, I believe, creates error, and the error is that it doesn't properly frame the question for the jury to decide and creates jury confusion. Therefore –

THE COURT: Slow down for the reporter.

MR. ROBERSON: For each of the different design defect ones – I'll take them one by one, unless the Court wants me to take the whole design defect items together.

THE COURT: Let's hear the defense on the alternative product or the lack of an alternative product instruction.

MR. JUDGE: We had a lengthy discussion with Kevin about this last night about a couple of problems. One is, the Model T is still on the road, and the second is that the instruction at the bottom of page 15 – bear in mind that a manufacturer is not obliged to design the safest possible product or a safer product or one as safe as others make so long as the design it has adopted is not unreasonably dangerous is completely contrary to what the plaintiff was just arguing, and this is New Hampshire law.

THE COURT: On the alternative product issue, the Court has decided not to give the instruction on "alternative products that have the same benefits but with less risk" That conflict is obviously one that

Attorney Jensen may argue at length in his closing, and the instruction that we are giving is a correct statement on the law, as is alternative products, but I'm persuaded by defense counsel's argument that the instruction might be confusing to the jury. It could be arguably – and that argument was advanced pretty strenuously in chambers last night when we spoke.

MR. JUDGE: Yes.

THE COURT: It could be taken as implying the existence of a safer alternative product equals defective condition, which is not the law, and the plaintiff has not identified any New Hampshire case with that specific language. It doesn't appear in the standard instructions, and it would be a departure from normal practice to include it in this case. Are you on your feet?

MR. JUDGE: I am, your Honor. I'm not sure how you want to proceed. I have a very minor addition that I wanted to do on page 12 that we got past.

THE COURT: We're not going page by page. We're just taking issue by issue. If we don't cover an issue that you want to cover by the time he's done, you can cover yours.

MR. JUDGE: Thank you, your Honor.

THE COURT: I'm trying to get these done by 10:00, but go ahead.

MR. ROBERSON: In regard to design defect there's also an issue –

THE COURT: You have to slow down for the reporter. What's the instruction you're talking about? Oh, defective design?

MR. ROBERSON: Defective design starting on page 15.

THE COURT: Right.

MR. ROBERSON: And that is the absence of any type of instruction that the alleged design defect is the inherent risk of SJS and TEN and other injury. Again, it might create jury confusion, and to a certain extent it obviously can be handled on argument. However, it would better help frame the defect in design section so that the jury can understand that that is an appropriate allegation of a defect under New Hampshire law.

THE COURT: Counsel?

MR. JUDGE: Well, first of all, we don't agree with that whole principle, but leaving that aside for a moment the sentence on –

THE COURT: Your view is that Buckingham is the law.

MR. JUDGE: Exactly.

THE COURT: And that's preserved. I mean, that's noted.

MR. JUDGE: The sentence on page 15, "A product is defective as designed if the magnitude of the danger outweighs the utility or usefulness of the product.", captures exactly the concept that he's talking about; and although we disagree with it, I think that is the law under Vautour – let me say it a different way. While we understand that the Court thinks that's the law under Vautour, I think the Court is actually past that theory.

THE COURT: The Court agrees with defense counsel's argument on this point. There does not need

to be a separate statement in the jury charge if plaintiff has alleged that the defect is the unreasonable danger.

The second paragraph of the defective design instruction, a product is defective as designed if the magnitude outweighs the utility or usefulness of the product, covers that issue sufficiently, and that's the reason the Court will give that instruction.

Attorney Roberson?

MR. ROBERSON: This is the new –

THE COURT: I want to make something clear about this discussion because I do want to get this jury in the box at 10:00. This is the time to argue what you think in the instructions is error. The time for persuading me what the instructions should be, which is a very appropriate conversation, has passed.

We have had three chambers conferences on this, and I really have tried to account for all of your positions. I've tried to find agreements where I could and give some relief to your arguments where I thought it was appropriate, and I wouldn't violate the law.

What I don't want to hear now is how I could do this better. I want to hear how my instructions are erroneous so I can put your objection on the record. Nothing more than that. I don't want to get into another "Robersarian" informal chambers conference on this, and I say that with all due respect. Go ahead.

MR. ROBERSON: In regards to the design defect instruction as it's set up right now – and this is the one thing we hadn't brought up before because we've been kicking it back and forth as to is this proper under New Hampshire law or not to have this as really two

questions or whether or not this should be one question that wraps it all up.

In taking a look at the New Hampshire cases in Thibault, Fortier, Vautour, all these other items, it was one single question, and we have a concern that it's fair under New Hampshire law because, first of all, it's never been done before. It's been split up. And second of all –

THE COURT: What possible basis do you have – do you know what the jury instructions were in all those cases?

MR. ROBERSON: Oh, no.

THE COURT: Well, how do you know it's never been split up? And by the way, it's not split up here. It's one instruction on defective design, and it accurately states on page 16 if the jury determines that Sulindac was unreasonably dangerous, it moves on to the warning, which is a hundred percent consistent with the cases you just mentioned, but I'm only asking this. You just said it's never been done. What is your basis for saying that?

MR. ROBERSON: Let me clarify the wording. The New Hampshire cases on point that cover this issue do not seem to indicate that it is a multi-tiered question. They seem to indicate that it is one unified question. Now, your Honor is correct, I have not pulled the jury charge to see if the particular instructions create kind of a cascading effect.

Quite frankly, we've been researching it. We've been trying to figure it out, and we've also been trying to figure out not only is it improper in the law, but we've been trying to figure out if it helps us or hurts us

from a practical step, and we can't figure that out, either.

So right now, you know, for the record, you know, we're asserting that there should be some type of clarity that this is all one big analysis and, you know, I apologize that we haven't had a chance to bring this up prior, your Honor.

MR. JUDGE: I must confess, I have no idea what he's talking about.

THE COURT: What he's saying is that – he's trying to say that the defective design should not be a two-step analysis. Analyze unreasonable danger, and then once you've found that, move on to the warning. He's saying that that should somehow be melded into a single question which – I don't know. I don't know. I guess to evaluate the danger – he's saying what he's always argued. Evaluate the danger, including the warning or because of the warning, not in spite of the warning.

MR. JUDGE: That's not what the cases say.

THE COURT: Of course not. The defective design on pages 15 and 16 of this jury charge capture the two layers of this question accurately. I will also note that to the extent some melding of these issues into a single holistic instruction are possible, no such language has been proposed by the plaintiff in this case. Attorney Roberson, what's your next argument?

MR. ROBERSON: In regards to the item that was removed from the prior charge on the bottom, the second half of the warning, a statement to the effect that under New Hampshire law even if the jury were to find the warning to be efficacious, it could still find the risk outweighs the benefit even with the warning.

THE COURT: You should say adequate, not efficacious, but point taken.

MR. ROBERSON: In that regard, first of all, the statement that was removed from the prior jury charge – which we would ask that to be placed in the record. The statement that was removed we do believe was a proper statement of New Hampshire law.

THE COURT: Yep.

MR. ROBERSON: We feel the removal of that sentence creates jury confusion and potentially raises the plaintiff's burden because the jury might be confused into thinking that if it finds the warning effective that the plaintiff can in no way still show that the risk outweighs the benefit.

Now, obviously we can, you know, state otherwise in arguments and the fact that defendant doesn't object or the Court doesn't stop us will give the jury some clue that that's a permissible inference they're allowed to raise; but nevertheless, the sentence that was removed was a proper statement of New Hampshire law and in its absence creates jury confusion and potentially raises the burden on plaintiff.

MR. JUDGE: Your Honor, this was a section that was discussed, again, at length in chambers. The Court indicated that I believe it was going to come out. It just confuses the whole issue. The way that the warning section is now set up is a proper statement of New Hampshire law. The offending sentence confuses a number of different propositions. Even if you took the expression "adequate warning" out of it and changed that into something like effective, what we have here is New Hampshire law and any changes to it would be beyond New Hampshire law.

THE COURT: Right.

MR. ROBERSON: A similar but separate argument–

THE COURT: Okay. Go ahead.

MR. ROBERSON: – in regards to its absence.

THE COURT: Well, wait a minute. Just give me a moment. On that one, Attorney Roberson is correct. I did take out the sentence that was in an earlier draft about how a product could be unreasonably dangerous even if it had an adequate warning. The sentence that we had used was really sort of a failure to warn instruction, and that would create some confusion. It referred to the label's adequacy, sort of a Comment K term which has been withdrawn as a defense in this case. It did not refer to the presence and efficacy to avoid unreasonable danger, which is the law that applies to this case, and so it was out of place in these instructions as far as the Court was concerned. It's a correct statement of the law that a product can be unreasonably dangerous even if it has an adequate warning; but adequacy is not a question before this jury. So to the extent you think you can go up there and argue that, by the way, I would tread carefully. Adequacy is not an issue before this jury. I want to avoid any suggestion to this jury that there's a duty to warn on Mutual's part because this is not a negligence case or even a products liability case that in some way implicates duty.

The bottom line is it's a failure to warn instruction as it was and that's why it was removed. This is not a failure to warn case.

You were about to make another point, Attorney Roberson.

MR. ROBERSON: Yes, and that is –

THE COURT: Oh, wait a minute. Did you want to add something to that point?

MR. JUDGE: I just want to emphasize another piece of that particular sentence. I just don't believe – and it's the jury's memory that will control this – that there has been any evidence about whether there would have been excessive cost to change the product or a loss of product efficiency. I don't believe that they–

THE COURT: I remember one question about that. I don't even remember if it got objected to.

MR. JUDGE: I can remember your Honor saying this guy didn't work for a pharmacy company and he's never been in the FDA. He can't possibly answer that question.

Now, whether I'm taking something that you said to a different question – we discussed this this morning. We remember one question. We think it was objected to, but the jury – I think the plaintiff needs to be careful about arguing whether there is any evidence – well, they can take the risk if the jury says no, there wasn't.

THE COURT: To make argument like that he runs the risk of the Court – you know, the hammer of God coming down with some kind of cautionary instruction. I guess that's how closing arguments are. Kevin, what's your memory of that, if you have one?

LAW CLERK – MR. JONES: There was no testimony about whether an unreasonable danger could have been eliminated without excessive costs.

THE COURT: Yeah, I think there was a question and an objection and I cut them off. That's my memory of it. All right. What's your next issue, Attorney Roberson?

MR. ROBERSON: A similar argument but slightly different. In the absence of that sentence, this jury could unreasonably believe that in regards to the paragraph – I want the record to be clear – I was arguing that prior sentence with the word adequate changed to efficacious or effective, which is what we had discussed in chambers.

THE COURT: All right.

MR. ROBERSON: The plaintiff understood and understands that the word adequate warning is not in this case and will be using effective and efficacious throughout their jury arguments.

THE COURT: All right.

MR. ROBERSON: Now, the issue –

THE COURT: So what's the next issue? Which instruction are you –

MR. ROBERSON: Still on 15 and still on the warning issue, and that is in its present state the plaintiff's understanding of New Hampshire law is that if the jury were to find the warning given is not effective, then their analysis should stop there. In other words, the risk/benefit analysis of the product with its warning requires a finding of the jury that the warning is effective.

Now, the phrase right now, "If you determine that Sulindac was unreasonably dangerous, you may consider the presence and efficacy or effectiveness of a warning to avoid risk of danger from foreseeable uses

of the product.", it doesn't clearly tell the jury, if you find the warning was not effective, you should not consider it, and we would request an instruction that clarifies –

THE COURT: You should not consider it?

MR. ROBERSON: Yes.

THE COURT: Or you should find for the plaintiff or something like that? I mean –

MR. ROBERSON: If you find the warning was not effective, you should not alter your risk/benefit analysis.

THE COURT: You mean not effective to avoid an unreasonable risk of danger?

MR. ROBERSON: Right.

THE COURT: The only way I would be open to that would be if I added, you know, if you find that a warning was not – that the warning was not effective to avoid an unreasonable risk of danger from foreseeable uses of the product, you should find for the plaintiff. However, if you find that it was effective in avoiding an unreasonable risk or danger, you should find for the defendant. If we do something, it's going to have to be even handed.

MR. ROBERSON: Well, you may consider – if you find that it was an effective warning, you may consider if it altered the risk/benefit analysis.

THE COURT: We can't get too – what do they do with that information? That's not going to help the jury.

MR. JUDGE: Your Honor, you already have this concept in here. The next sentence, "The plaintiff must

prove that the product was unreasonably dangerous even with this warning."

THE COURT: Yeah. I'm considering adding a sentence, though, that captures the idea – a little bit of the idea that Attorney Roberson – I'm going to talk it over with my law clerks about it, but that one I'm either granting or denying. At this point it's under advisement.

MR. ROBERSON: I would request, your Honor, that the Court be clear. If it adds such a sentence –

THE COURT: You will know about it ahead of time.

MR. ROBERSON: Not only that, it's not an all or nothing proposition. If the warning is effective, plaintiff still believes that it's effectiveness doesn't create an automatic defense win.

THE COURT: If the jury finds that it's effective to avoid an unreasonable risk of danger, it does end the case, yes. That's the law.

MR. JUDGE: Right.

THE COURT: But if they find that it doesn't, it also ends the case.

MR. JUDGE: Right, but that concept is already in there.

THE COURT: You're right. It's there in that last sentence.

MR. JUDGE: It's in the sentence before that, also. You may consider the presence and efficacy of a warning –

THE COURT: I know.

MR. JUDGE: – to avoid an unreasonable risk of danger.

THE COURT: I'm just considering the possibility of putting a finer point on that because finer points like that are often in jury instructions. If you bring it right down to the brass tacks – if you get to this point and you find X, you find for one side. If you find Y, you find for the other. I'm considering whether I should do that here.

MR. ROBERSON: If your Honor is going to put it as X or Y, automatic win or automatic loss, the plaintiff would object that is not proper New Hampshire law; but we do think the absence of an effective warning means they should not consider it.

THE COURT: Okay.

MR. JUDGE: Well, they have to consider it in order to determine whether or not it is effective.

THE COURT: It's not going to go that way. You need not worry about that.

MR. JUDGE: Well, just for the record, we don't want it to go any way.

THE COURT: I know you don't. I know you don't.

* * *

MR. ROBERSON: I requested only the first portion of it. That if it's not --

THE COURT: You only requested the part that helps you. Okay.

MR. ROBERSON: Which we believe is accurate New Hampshire law.

THE COURT: You don't think the second sentence, however, is accurate?

MR. ROBERSON: No, we don't, your Honor.

THE COURT: Okay. I'll leave it to somebody's imagination to figure out why that could be the case the first part is accurate. It's only the comments in the first statement, right?

MR. ROBERSON: Right.

MR. JUDGE: Just for the sake of it, I'm going to say Buckingham.

THE COURT: Buckingham. Right. Okay. Let's get the jury.

(IN COURT - JURY PRESENT)

THE COURT: Members of the jury, as you know, the plaintiff has rested her case. The defense has rested its case. It is now time for me to give you instructions.

Before I do, I need to ask if any of you have had any conversations with each other or anyone else about this case since the court went into recess? Have any of you conducted any independent research or investigation on any matter involved in this case in any media? No response. All right. Then we'll proceed.

Just so you know how to plan out your day in your own head, the plan is to give you the jury instructions, and you have copies in front of you now. After that, we'll take the lunch break. After the lunch break, we'll hear what's called closing arguments or summation, and then the case will be given to you, the jury, to deliberate.

You're free to follow along and read, you each have a copy, or you're free to put them aside and just listen to me. Your best bet is probably to focus on me and what I'm saying and try to understand it because you

will have these copies with you and you can refer to them any time during your deliberations.

At this stage of the trial it is the duty of the Court to instruct you on the principles of law that you will apply in deciding this case. It is your duty to follow these instructions during your deliberations. You should not single out any one instruction, but instead apply these instructions as a whole to the evidence in this case.

You are the sole and exclusive judges of the facts. You must weigh the evidence that has been presented impartially, without bias, without sympathy, and without prejudice, for or against any party. You must make a determination as to what the facts are, what the truth is, based upon the evidence presented in this case. You will decide the case by applying the law as it is given to you in these instructions to the facts as you find them to be from the evidence.

The mere fact that the plaintiff may have brought a lawsuit is not, in and of itself, a reason to render a verdict in her favor. Bringing a lawsuit is merely the formal means of introducing the matter of controversy into court. The complaint which initiates the action and the allegations contained in it are not evidence of liability or fault on the part of the defendant. Your verdict must be based solely on the evidence and the law.

In determining what the facts are, what the truth is, you must necessarily assess the credibility of each witness and determine what weight you will give each witness's testimony. By credibility, we mean the believability or truthfulness of a witness. You should carefully scrutinize all of the testimony given, the circumstances under which each witness has testified,

and every matter in evidence which tends to show whether a witness is worthy of belief or not worthy of belief.

Consider each witness's intelligence, motive and state of mind, and demeanor and manner while testifying. Consider the witness's ability to observe or to know the matters about which that witness has testified and whether the witness impresses you as having accurate recollection of those matters.

Consider whether the witness had any reason for telling the truth or not telling the truth, whether the witness had an interest in the outcome of the case, whether the witness had any friendship, relationship, or animosity toward another individual or individuals involved in the case, whether the witness's testimony was consistent or inconsistent with itself or with the testimony of other witnesses. Consider the extent to which, if any, the testimony of each witness is either supported or contradicted by other evidence in the case.

The testimony of a witness may be discredited or, as we sometimes say, impeached, by showing that the witness previously made statements which are different from, or inconsistent with, his or her testimony here in the court. Inconsistent or contradictory statements which are made by a witness outside of court may be considered only to discredit or impeach the credibility of the witness and not to establish the truth of these earlier out-of-court statements.

If a prior inconsistent statement was made under oath in a deposition, however, it may be introduced not only to impeach the credibility of the witness but also as substantive evidence of the truth of the statement.

You must decide what weight, if any, should be given to the testimony of a witness who has made prior inconsistent or contradictory statements. In making this determination you may consider whether the witness purposely made a false statement or whether it was an innocent mistake; whether the inconsistency concerned an important fact, or whether it had to do with a small detail; whether the witness had an explanation for the inconsistency, and whether that explanation appealed to your common sense.

After assessing the credibility of each witness, you will assign the testimony of each witness, both under direct and cross-examination, such weight as you deem proper. You are not required to believe the testimony of any witness simply because that witness was under oath. You may believe or disbelieve all or part of the testimony of any witness simply because -- strike that. You may believe or disbelieve all or part of the testimony of any witness. It is within your province to determine what testimony is worthy of belief and what testimony may not be worthy of belief.

The testimony of certain witnesses was shown to you on video. When this video testimony was taken, the witnesses took an oath that is identical in purpose to the oath given to the witnesses who testified before you in the courtroom. Both parties were given the opportunity to ask questions of the witnesses during the video testimony, and video testimony should be considered by you as you would consider any other testimony, giving it the weight you think it deserves.

Certain witnesses have testified in this case as experts because of their special training, education, skills or knowledge. When a case involves a matter requiring special knowledge or skill not ordinarily

possessed by the average person, an expert is permitted to state his opinions or her opinions of the information for the assistance of the Court and the jury. An expert's opinion is subject to the same rules concerning reliability as the testimony of any other witness.

The opinions stated by the experts who testified before you were based on particular facts the experts observed, learned from others, learned from materials that they reviewed, or facts that counsel asked the experts to assume.

You may reject an expert's opinion if you decide that the facts are different from the facts that formed the basis of the expert's opinion, or if you decide that the expert's opinion is based on misinformation, or if you decide that the expert lacks the qualifications to render a reliable opinion.

You may consider whether or not the expert took advantage of the opportunity to make a thorough investigation before rendering an opinion. You may also reject an expert's opinion if after careful consideration of all of the evidence in the case, expert and other evidence, you disagree with the opinion.

In other words, you are not required to accept an expert's opinion. You may accept all, part, or none of the testimony of an expert, and you are not required to accept any expert's opinion as to the issues you ultimately have to decide.

In examining a witness, a lawyer may ask a hypothetical question. A hypothetical question is one in which a witness is asked to assume certain facts are true and to give an opinion based upon that assumption. It is for you to decide from all of the

evidence whether or not the facts so assumed have been proved. If you do not think the facts assumed have been proved by a preponderance of the evidence, you will disregard the answer.

If, however, you think the facts assumed have been established by a preponderance of the evidence, the answer may be considered by you. Such an answer is essentially opinion evidence, and like all other evidence of this nature, you may accept it or reject it according to your best judgment.

What is evidence? There are two types of evidence that you may properly use in deciding a case. Direct evidence is the testimony given by a witness about what that witness has seen, heard or observed, or what that witness knows based on personal knowledge. Direct evidence also includes any exhibits that have been marked.

Evidence also may be used to prove a fact by inference. This is referred to as circumstantial evidence. In other words, from examining direct evidence you may be able to draw certain inferences which are reasonable and justified in light of your daily experience. Such inferences constitute circumstantial evidence. A good example is if you look outside the window and you see the rain coming down and you say, it's raining. If you look outside the window and see that the ground is wet and there are puddles, you say it rained, and you're making that based on an inference. Those puddles and the wet ground are circumstantial evidence of the fact that it rained. That's all it is. Circumstantial evidence may be given the same weight by you as direct evidence.

The evidence in this case consists of the sworn testimony of the witnesses, all of the exhibits received

in evidence, any facts that the parties have agreed or stipulated to and any facts that I have instructed you to find. You must consider all of the evidence, no matter which side produced it or elicite it, because neither side has an exclusive right to the testimony of particular witnesses or to the evidence that is presented.

You should be mindful that any evidence which I have instructed you to consider for a limited purpose must be considered for that limited purpose only.

What is not evidence? Certain things are not evidence and cannot be considered by you as evidence. Arguments and statements by lawyers are not evidence. That means questions and statements by lawyers, they're not evidence. What they have said in their opening statements, closing arguments and at other times is intended to help you interpret the evidence, but it is not evidence itself. If the facts as you remember them differ from the way the lawyers have stated them, your memory controls.

If the law as stated by the lawyers differs from the law as stated by the Court, you must take the law from the Court. That's me. The only person who can tell you the law in this case is the Court: You are not to be concerned with the wisdom of any rule of law as stated by the Court. Regardless of any opinion you may have as to what the law ought to be, it would be a violation of your sworn duty to base a verdict upon any other view of the law that has been given -- any other view than the view that has been given in the instructions of the Court, these instructions, just as it would be a violation of your sworn duty as judges of the facts to base a verdict on anything but the evidence in this case. That's why I asked you every day if you've

conducted an independent investigation or research. Any facts that came from those sources would be a violation of your sworn duty to consider.

Questions and objections by lawyers are not evidence, unless the witness adopts the facts set forth in the question. Lawyers have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by objections or by my ruling on objections. It is the responsibility of the Court to rule on objections, and the Court has not intended to indicate in any way by its rulings or by what it has said what the verdict should be in this case. The Court in this case, as in all cases, is completely neutral and impartial, and it leaves it to the jury to decide the case based on the facts as you find them to be and the law as the Court will give it to you.

Testimony that has been excluded or stricken,or that you have been instructed to disregard, is not evidence and must not be considered. Anything you have seen or heard when the Court was not in session is not evidence. You are to decide the case solely on the evidence received at trial in this courtroom.

A stipulation is an agreement -- it is evidence, and it's an agreement between the parties as to the truth of a particular fact. If the parties have stipulated to a fact, you must consider that fact as having been proved.

Judicial notice. The Court may take judicial notice of facts which I regard to be as common knowledge. The example I used, I think, when I told you during the trial is that Pleasant Street runs from east to west in the City of Concord right by this courthouse. That is beyond dispute, incontrovertible, and the Court takes

it as common knowledge and that's the type of thing the Court takes judicial notice of. By my taking judicial notice of these facts, neither party is required to introduce formal evidence to prove them. You must consider facts judicially noticed as having been proved. The significance of such facts and your ultimate findings in this case, however, is up to you to decide.

As a reminder, the Court took judicial notice of certain Food and Drug Administration, FDA, requirements for drug labels, which I will describefor you later in these instructions.

The Court also took judicial notice that the National Drug Code, or NDC number, for Mutual Pharmaceutical Company's 200 milligram Sulindac tablets is 53489-479-01.

Now, in a civil case, such as this, the party who makes a claim has the burden of proving that claim. This is referred to as the burden of proof. The party having the burden of proof must satisfy you that her claims on an issue are more probably so than not. This is referred to as proof by a preponderance of the evidence.

You probably have only heard of proof beyond a reasonable doubt. The party having the burden of proof does not have to prove her claims beyond a reasonable doubt as is required in a criminal case. This is not a criminal case. This is a civil case. Nor does the party with the burden of proof have to prove her claims to a certainty. To meet the burden of proof, a party must prove that her claims are more probably so than not.

As an example, imagine in your mind the scales of justice because you hold the scales in this case. Put all

of the credible evidence on the scales,with the evidence in favor of the party having the burden of proof on one side of the scales and the evidence in favor of the other party on the other side. If the scales tip, ever so slightly, for the party having the burden of proof, then on that issue the party has sustained his or her burden. If the scales tip in favor of the other side, or remain in balance, then the burden of proof has not been satisfied.

As I explained to you at the beginning of the trial, this case is a civil action brought by the plaintiff, Karen Bartlett, against the defendant, Mutual Pharmaceutical Company, which I will sometimes refer to as Mutual. Mrs. Bartlett alleges that she took a generic prescription drug, known as Sulindac, for pain in her shoulder, and that the drug caused her to suffer a condition known as Stevens-Johnson Syndrome, SJS, and toxic epidermal necrolysis or TEN, which allegedly resulted in significant injuries. Mrs. Bartlett has brought a claim for strict products liability against Mutual, a manufacturer of the drug Sulindac.

There can be occasions where a person is injured and another person or entity is legally responsible or liable, in which case the injured person is entitled to recover damages. There can also be occasions where a person is injured but no one is legally responsible or liable, in which case the injured person is not entitled to recover damages. Thus, it is important that you understand the particular legal claim that Mrs. Bartlett is making against Mutual in this case, which Mrs. Bartlett has the burden of proving by a preponderance of the evidence. I will now discuss the elements of that legal claim with you.

Before moving on to that discussion, however, I note that Mrs. Bartlett brought her claim against a corporation, Mutual Pharmaceutical Company. A corporation can be held liable to a plaintiff just as an individual can.

The fact that the defendant is a corporation should play no other role in your deliberations, just as the fact that Mrs. Bartlett is an individual should play no role in your deliberations. All parties, whether individuals or corporations, have equal standing in the law.

Now the claim. As I mentioned, Mrs. Bartlett has brought a claim against Mutual for strict products liability. In order to recover on her claim for strict products liability, Mrs. Bartlett must prove each of the following six elements by a preponderance of the evidence:

1. That Mutual was in the business of selling Sulindac.

2. That Sulindac's design was in a defective condition unreasonably dangerous to consumers.

3. That the defective condition existed when Mutual sold the product.

4. That the product reached Mrs. Bartlett without substantial change in the defective condition in which it was sold.

5. That the purpose and manner of Mrs. Bartlett's use of Sulindac was reasonably foreseeable by Mutual; and

6. That the defective condition caused or substantially caused injury to Mrs. Bartlett.

Mrs. Bartlett must prove, first, that Mutual was in the business of selling Sulindac. It is not necessary for

Mrs. Bartlett to prove that Mutual sold Sulindac directly to her or directly to the pharmacy that filled her prescription. It is sufficient if Mrs. Bartlett proves that Mutual placed Sulindac into the stream of commerce.

A defect in design occurs when the product has been manufactured in conformity with the manufacturer's design but the design itself presents unreasonable danger to consumers.

In deciding whether Sulindac's design presented unreasonable danger, you should consider the usefulness and desirability of the product to the public as a whole. A product is defective as designed if the magnitude of the danger outweighs the utility or usefulness of the product.

You should also consider whether Sulindac's risk of danger, if any, could have been reduced without significant impact on the product's effectiveness or its manufacturing cost. Liability may exist if the manufacturer did not take available and reasonable steps to lessen or eliminate the danger of even a useful and desirable product.

Bear in mind that a manufacturer is not obliged to design the safest possible product, or a safer product, or one as safe as others make, so long as the design it has adopted is not unreasonably dangerous.

By the same token, you may find that a product's design was unreasonably dangerous even if the plaintiff has not presented evidence of analternative design that could have made the product safer.

Now, if you determine that Sulindac was unreasonably dangerous, you may consider the presence and efficacy or effectiveness of a warning to

avoid an unreasonable risk of danger from foreseeable uses of the product. The plaintiff must prove that the product was unreasonably dangerous even with its warning.

If you determine that Sulindac was unreasonably dangerous and that a warning was not present and effective to avoid that unreasonable danger, then you must find Mrs. Bartlett has proven this element of her claim, a defect in design. However, if you determine that Sulindac was unreasonably dangerous, but that a warning was present and effective to avoid that unreasonable danger, then you must find for Mutual.

A manufacturer is not responsible for injuries caused by a product's defective condition unless the purpose and manner of the plaintiff's use of the product were reasonably foreseeable by the manufacturer. In terms of foreseeability, we are talking about reasonable foreseeability and not some sort of prophetic vision as to what might conceivably happen. A manufacturer may be held liable even if the user employs the product in an unintended but foreseeable manner.

A product's defective condition is a legal cause of the plaintiff's injuries if it directly and in natural and continuous sequence produces or substantially contributes to producing the injuries so that it can reasonably be said that but for the defective condition the injuries would not have occurred.

In determining whether the defective condition was a legal cause of the plaintiff's injuries, you need not find that the defective condition was the sole cause of the injuries, but only that it was a substantial factor in bringing about the injuries, even though other factors may have contributed to the cause of the injuries.

Adverse event reporting rates. You have heard testimony about the alleged number of adverse event reports of SJS/TEN associated with Sulindac and other drugs and about their alleged "reporting rates" In the context of this trial, a "reporting rate" means the number of adverse event reports for a drug divided by the number of prescriptions for the drug. You should not confuse "reporting rate" with the rate at which SJS/TEN actually occurs with a drug. Those are two different concepts. You have not heard any testimony about the actual occurrence rate of SJS/TEN with Sulindac individually, as compared with other drugs, except for those drugs that allegedly do not have any risk of SJS/TEN.

FDA approval. You have heard evidence that the Food and Drug Administration, the FDA, approved Sulindac as safe and effective for its intended uses, that the FDA approved Sulindac's label or "package insert" in place at the time of Mrs. Bartlett's prescription, and that the FDA required changes to that label and the labels of all other NSAIDs after the time of Bartlett's prescription. You may consider that evidence, along with all of the other evidence presented, in evaluating whether Mrs. Bartlett has proven her claim under the law as set forth in these instructions.

Neither the FDA's approval of the drug and its label, nor its requirement of label changes, is necessarily conclusive or controlling on any issue that you've been asked to decide. You may give it as much or as little weight as you think it deserves, in light of all of the evidence, under the law as set forth in these instructions.

As I mentioned earlier, if you determine that Sulindac was unreasonably dangerous, you may consider the presence and efficacy of a warning to avoid an unreasonable risk of danger from foreseeable uses of the product. In evaluating that issue, you may consider the FDA's requirements for drug labels, along with all the other evidence presented. Compliance or non-compliance with FDA legal requirements is not necessarily conclusive or controlling on that issue. You may give such evidence as much or as little weight as you think it deserves, in light of all of the evidence.

As I instructed you during the trial, the Court has taken judicial notice of the following FDA requirements for labels:

1. The label must contain a summary of the essential scientific information needed for the safe and effective use of the drug.

2. The label must be informative and accurate and neither promotional in tone, nor false or misleading in any particular.

3. The label's "Adverse Reactions" section must list the adverse reactions that occur with the drug and with drugs in the same pharmacologically active and chemically related class, if applicable.

An adverse reaction is an undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence.

In this listing, adverse reactions may be categorized by organ system, by severity of the reaction, by frequency, or by toxicological mechanism, or by a combination of these, as appropriate. If frequency information from adequate clinical studies is available,

the categories and the adverse reactions within each category shall be listed in decreasing order of frequency. An adverse reaction that is significantly more severe than the other reactions listed in the category, however, shall be listed before those reactions, regardless of its frequency.

4. The label's "Warnings" section must describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

A serious adverse reaction is one that results in death, an immediate risk of death, inpatient hospitalization or prolongation of existing hospitalization, or a persistent or significant disability or incapacity. A disability is a substantial disruption of a person's ability to conduct normal life functions.

The frequency of these serious adverse reactions and the approximate mortality and morbidity rates for patients experiencing a reaction, if known and important to safe and effective use of the drug, must be expressed as provided under the label's Adverse Reactions" section.

That last point I made, the frequency of these serious adverse reactions, is the fifth requirement of FDA labeling. I numbered the first four, and I neglected to say five before that last one.

The FDA may also require special problems, particularly those that may lead to death or serious injury, to be placed in a prominently displayed box on the drug label. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a box warning in the absence of

clinical data. If a boxed warning is required, its location will be specified by the FDA.

The FDA also may require that a drug label include a medication guide for patients if the FDA determines that one or more of the following three circumstances exists:

1. That the drug is one for which patient labeling could help preserve -- strike that. The drug is one for which patient labeling could help prevent serious adverse effects.

2. The drug has serious risk, relative to benefits, of which patients should be made aware because information concerning the risk could affect a patients' decision to use, or to continue to use, the drug.

3. The drug is important to health, and patient adherence to directions for the use -- for its use is crucial to the drug's effectiveness.

The medication guide. As I instructed you during the trial, the medication guide is designed and intended to provide information to patients about a prescription drug's side effects if the FDA determines that such a guide is appropriate under the regulations that I have just described for you. In considering evidence regarding the medication guide, you shall bear in mind -- you should bear in mind that under New Hampshire law, which applies in this case, a prescription drug's warning is designed and intended for prescribing doctors, not for patients. Prescribing doctors decide what information they will read to educate themselves about the drugs they prescribe, and it is their decision whether or not to convey that information to their patients.

Now, this claim is focused on the product Sulindac, whether its design was in a defective condition unreasonably dangerous to consumers and whether that defective condition caused Mrs. Bartlett's injuries. This claim is not about whether Mutual, Mrs. Bartlett, or the doctor who prescribed the drug knew of Sulindac's safety risks or any of their conduct in seeking or responding to such knowledge. Those issues are not relevant to this case, and you should put them out of your mind.

Damages. If you find that Mrs. Bartlett has sustained her burden of proving her claim for strict products liability, then the next step in your deliberations is to consider the issue of damages. However, if you find that Mrs. Bartlett has failed to prove her claim by a preponderance of the evidence, then you will conclude your deliberations. You must not compromise between the liability issue and the damage issue. You must determine the issue of liability first. You must determine -- you should proceed to the damage issue only if you havedetermined that Mutual's liability has been proven.

Mrs. Bartlett has the burden of proving that it is more probable than not that the damages she seeks were caused by Sulindac's defective condition. Mrs. Bartlett also has the burden of proving the nature and extent of her damages and the amount of money representing adequate compensation with such certainty as the nature of the claim and the circumstances permit.

If you find that Mrs. Bartlett is entitled to damages in accordance with these instructions, then you should award a sum of money which will fairly compensate

her for her injuries resulting from Sulindac's defective condition. The award must be full, fair, and adequate. It must not be cheap or miserly, nor should it be a reward or a prize. The purpose of civil law is not to punish defendants for wrongdoing, but to compensate those who are injured in such amounts as the evidence justifies. Damages should not be awarded out of sympathy, passion, or prejudice, nor should damages be based on a guess or speculation. Damages must be based on the law and the evidence.

Now, in determining the amount of damages to award Mrs. Bartlett, you may draw such inferences as are justified by your common experiences and observations of mankind from the evidence of the nature of the injuries and the results thereof. You may also consider whether it is more probable than not that her damages will continue into the future as a direct, natural, and probable consequence of Sulindac's defective condition and, if so, award her full, fair, and adequate compensation of those future damages.

Now, in awarding damages, the following maybe considered:

1. The reasonable value of medical -- that's hospital, nursing -- medical care, services, and supplies reasonably required and actually given to date in the treatment of Mrs. Bartlett. The parties have stipulated that Mrs. Bartlett's past medical expenses as a result of her SJS/TEN are $1,250,000.

2. The reasonable value of medical care, services, and supplies that will probably be required and given in the future treatment of Mrs. Bartlett.

3. The present value of lost wages that Mrs. Bartlett probably would have earned to date, and

probably would earn in the future, if she had not been injured. While there's no fixed rule to calculate the amount of damages to be recovered for loss of earning capacity, you may consider evidence that tends to show that as a result of her injuries the plaintiff's ability to earn money has been impaired or diminished.

4. Reasonable compensation for pain and suffering experienced to date and which will probably be experienced in the future. This includes compensation for physical pain, discomfort, fears,anxiety, mental and emotional distress, and loss of enjoyment of life. That is, the inability to carry on and enjoy life in a way she would have had the accident not occurred.

There is no precise mathematical formula by which to fix reasonable compensation for pain and suffering, nor is the opinion of any witness required as to the amount of such reasonable compensation. In making an award for pain and suffering, you should exercise your reasonable judgment. The damages you determine have to be full, fair, and adequate in light of the evidence.

If you find from the evidence that Mrs. Bartlett is likely to continue to suffer damages in the future, you may consider her life expectancy; that is, the number of years she is likely to continue to suffer damages. According to a table of mortality,the life expectancy of a female aged 50.1 years is 32.6 additional years. This figure is not binding upon you. It is an estimate based on experience of persons who have reached that age.

However, this figure may be considered by you in connection with other evidence related to the possible life expectancy of Mrs. Bartlett, including evidence of her occupation, health, habits, and other activities and

circumstances, bearing in mind that many persons live longer and many die sooner than the average.

The purpose of an award of damages is to compensate the plaintiff for her loss, not to punish the defendant. You are not permitted to award punitive damages or any other money damages for the purpose of punishing Mutual or making an example of it for the public good or for the purpose of preventing Mutual and others from similar conduct.

During this trial you heard Mutual's counsel ask some questions of witnesses about whether certain health plans and insurance companies have listed Sulindac on a formulary or a list of approved drugs. You may consider the testimony given in response to those questions only in evaluating whether Sulindac's design was in a defective condition unreasonably dangerous to consumers. You may not, however, consider the evidence strike that.

You may not, however, consider the existence or nonexistence of health insurance or any other kind of insurance coverage held by either party in your determination of damages or any other issue in this case.

Now, if an amount of damages has been or is mentioned by Mrs. Bartlett's counsel, that is not evidence in this case. A specific request for a total dollar amount made by the plaintiff's counsel is simply a request for recovery. In the event you find for Mrs. Bartlett, the amount of the verdict must be based solely on the evidence presented during the course of the trial and the law which I have given to you.

It is the duty of a person who has been injured to use reasonable effort, without undue risk or expense or

humiliation in caring for her injuries, and reasonable means to prevent their aggravation or accomplishing here -- strike that. I need to restate that. It is the duty of a person who has been injured to use reasonable effort, without undue risk or expense or humiliation in caring for her injuries, and reasonable means to prevent their aggravation and accomplish healing. When a person does not use a reasonable effort to care for her own injuries and those injuries are aggravated as a result of such failure, the responsibility of another who is legally liable or responsible for the original injury is limited to the amount of damage that would have been suffered had the injured person herself exercised the effort required of her. You should not include in the verdict such damages, if any, that Mrs. Bartlett could have avoided by reasonable effort, without undue risk or expense.

Now, the verdict form. There will be a form given to you along with a set of instructions. In the verdict form, the first question you will be asked is whether you find that Mrs. Bartlett has proven her claim for strict products liability by a preponderance of the evidence.

If your answer to that question is no, you must conclude your deliberations. If your answer to that question is yes, you will then be asked how much compensatory damages you award to Mrs. Bartlett in each of the following categories, as I described the to you just a few minutes ago (1) past medical expenses; (2), future medical expenses; (3), lost wages; and (4), pain, suffering, and loss of enjoyment of life.

The principles of law set forth in these instructions are intended to guide you in reaching a fair and just result in this case, which is important to the parties.

You are to exercise your judgment and common sense without prejudice, without sympathy, but with honesty and with understanding. You should be conscientious in your determination of a just result in this case because that is your highest duty as officers of this court.

When you retire to the jury room, you should elect one member of the jury as your foreperson. That individual will act very much like a chairperson of a committee, seeing to it that the deliberations are conducted in an orderly fashion and that each juror has a full and fair opportunity to express his or her views, positions and arguments on the evidence and the law.

The verdict must represent the considered judgment of each juror. In order to return a verdict,it is necessary that each juror agree thereto. Your verdict must be unanimous.

It is your duty as jurors to consult with one another and to deliberate with a view to reaching agreement, if you can do so without violence to individual judgment. Each of you must decide the case for yourself, but do so only after an impartial consideration of the evidence in the case with the other jurors.

In the course of your deliberations, do not hesitate to reexamine your own views and to change your opinion if convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of the evidence solely because of the opinion of the other jurors or merely for the purpose of returning a verdict.

You should also take as much time for deliberations in this case as you consider to be necessary and appropriate.

You were permitted to take notes during this trial, and I want to remind you of the instructions that I gave you about your notes. Do not use your notes as authority to persuade other jurors. Your notes should be used only as an aid to your own memory and must not be used as authority to persuade theother jurors of what the evidence was during trial.

You might have made an error or mistake in recording what you have seen or heard. In the end, each juror must rely on his or her own recollection or impression as to what the evidence was. Your notes are not official transcripts of the testimony.

Remember at all times that you are not partisans. You are judges, judges of the facts. Your sole interest is to seek the truth from the evidence in this case.

If during your deliberations it becomes necessary to communicate with the Court, with me, you may do so only in writing, signed by the foreperson or by one or more members of the jury. Give that note to the court security officer, who will bring it to the Court's attention. No member of the jury should ever attempt to communicate with the Court, except by a signed writing, and the Court will communicate withthe jury on anything concerning the case either in writing or orally in the courtroom.

Remember that you are not to tell anyone, including the Court, how the jury stands, numerically or otherwise, on matters that you are deciding until after you have reached a unanimous verdict or have been discharged.

Nothing said in these instructions, or anything else I have said during the trial, is intended to suggest or to convey in any way or manner what your verdict should be. The verdict is the sole and exclusive duty and responsibility of the jury. The Court is neutral and impartial in this matter and does not take sides.

When you have completed the verdict form according to these instructions and the instructions on the form, you will have concluded your deliberations and arrived at a verdict. At that point the foreperson should sign and date the verdict form and then notify the court security officer, and you will be returned to the courtroom where the foreperson will render the verdict orally.

Now, those are your instructions. I'll give you a very brief one or two minutes more after you hear closing arguments, but that is the general jury charge, the general instructions on the law. Do counsel need to approach?

There being no need to approach, Deb, let's excuse the jury. We will take the lunch break, and then you will hear the closings.

(IN COURT - NO JURY PRESENT)

THE COURT: Counsel?

MR. JENSEN: Would you or Kevin like a fixed version of my PowerPoint? I have it on a stick.

THE COURT: Sure. I assume you've made the adjustments we asked you to make.

MR. JENSEN: Yes.

THE COURT: We'll take one. Now, we'll give them the lunch break and we'll do closings. Closings are going to take the better part of the afternoon,

obviously. I know at least one of them will be lengthy. If we have time this afternoon, we'll take up the motions, the Rule 50 motion and your motions to strike, but we'll certainly-- we'll hear full argument on those and let you put whatever you need to put on the record, and we will do that while the jury deliberates.

* * *

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v. Civil No. 08-cv-358-JL

Mutual Pharmaceutical Company, Inc.

JURY INSTRUCTIONS

INTRODUCTION

At this stage of the trial it is the duty of the court to instruct you on the principles of law that you will apply in deciding this case. It is your duty to follow these instructions during your deliberations. You should not single out any one instruction but instead apply these instructions as a whole to the evidence in this case.

JURY SOLE JUDGES OF FACT

You are the sole and exclusive judges of the facts. You must weigh the evidence that has been presented impartially, without bias, without sympathy, and without prejudice, for or against any party. You must make a determination as to what the facts are, what the truth is, based upon the evidence presented in the case. You will decide the case by applying the law as it is given to you in these instructions to the facts as you find them to be from the evidence.

The mere fact that the plaintiff may have brought a lawsuit is not, in and of itself, a reason to render a verdict in her favor. Bringing a lawsuit is merely the formal means of introducing the matter of controversy into court. The complaint which initiates the action and the allegations contained in it are not evidence of liability or fault on the part of the defendant. Your verdict must be based solely on the evidence and the law.

CREDIBILITY OF WITNESSES

In determining what the facts are, what the truth is, you must necessarily assess the credibility of each witness and determine what weight you will give to each witness's testimony. By credibility we mean the believability or truthfulness of a witness.

You should carefully scrutinize all the testimony given, the circumstances under which each witness has testified, and every matter in evidence which tends to show whether a witness is worthy of belief or not worthy of belief. Consider each witness's intelligence, motive and state of mind, and demeanor and manner while testifying. Consider the witness's ability to observe or to know the matters about which that witness has testified and whether the witness impresses you as having an accurate recollection of those matters. Consider whether the witness had any reason for telling the truth or not telling the truth, whether the witness had an interest in the outcome of the case, whether the witness had any friendship, relationship, or animosity toward other individuals involved in the case, whether the witness's testimony was consistent or inconsistent with itself or with the testimony of other witnesses. Consider the extent to which, if any, the testimony of each witness is either supported or contradicted by other evidence in the case.

The testimony of a witness may be discredited or, as we sometimes say, impeached, by showing that the witness previously made statements which are different from, or inconsistent with, his or her testimony here in court. Inconsistent or contradictory statements which are made by a witness outside of court may be considered only to discredit or impeach the credibility of the witness and not to establish the truth of these earlier out-of-court statements. If a prior inconsistent statement was made under oath in a deposition, however, it may be introduced not only to impeach the credibility of the witness but also as substantive evidence of the truth of the statement.

You must decide what weight, if any, should be given to the testimony of a witness who has made prior inconsistent or contradictory statements. In making this determination you may consider whether the witness purposely made a false statement or whether it was an innocent mistake; whether the inconsistency concerns an important fact, or whether it had to do with a small detail; whether the witness had an explanation for the inconsistency, and whether that explanation appealed to your common sense.

After assessing the credibility of each witness you will assign to the testimony of each witness, both under direct and cross-examination, such weight as you deem proper. You are not required to believe the testimony of any witness simply because that witness was under oath. You may believe or disbelieve all or part of the testimony of any witness. It is within your province to determine what testimony is worthy of belief and what testimony may not be worthy of belief.

VIDEO TESTIMONY

The testimony of certain witnesses was shown to you on video. When this video testimony was taken, the witnesses took an oath that is identical in purpose to the oath given to the witnesses who testified before you in the courtroom. Both parties were given the opportunity to ask questions of the witnesses during video testimony. Video testimony should be considered by you as you would consider any other testimony, giving it the weight you think it deserves.

EXPERT WITNESSES

Certain witnesses have testified in this case as experts because of their special training, education, skills or knowledge.

When a case involves a matter requiring special knowledge or skill not ordinarily possessed by the average person, an expert is permitted to state his opinion for the information and assistance of the court and jury. An expert's opinion is subject to the same rules concerning reliability as the testimony of any other witness.

The opinions stated by the experts who testified before you were based on particular facts the experts observed, learned from others, learned from materials that they reviewed, or facts that counsel asked the experts to assume.

You may reject an expert's opinion if you decide that the facts are different from the facts that formed the basis of the expert's opinion, or if you decide the expert's opinion is based upon misinformation, or if you decide the expert lacks the qualifications to render a reliable opinion. You may consider whether or not the expert took advantage of the opportunity to make a thorough investigation before rendering an opinion. You may also reject an expert's opinion if, after careful consideration of all the evidence in the case, expert and other, you disagree with the opinion.

In other words, you are not required to accept an expert's opinion. You may accept all, part, or none of the testimony of an expert. And you are not required to accept any expert's opinion as to the issues you ultimately have to decide.

HYPOTHETICAL QUESTIONS

In examining a witness, a lawyer may ask a hypothetical question. A hypothetical question is one in which a witness is asked to assume that certain

facts are true and to give an opinion based upon that assumption.

It is for you to decide from all of the evidence whether or not the facts so assumed have been proved. If you do not think the facts assumed have been proved by a preponderance of the evidence, you will disregard the answer.

If, however, you think the facts assumed have been established by a preponderance of the evidence, the answer may be considered by you. Such an answer is essentially opinion evidence, and like all other evidence of this nature, you may accept or reject it, in whole or in part, according to your best judgment.

WHAT IS EVIDENCE

There are two types of evidence that you may properly use in deciding a case.

Direct evidence is the testimony given by a witness about what that witness has seen, heard or observed, or what that witness knows based on personal knowledge. Direct evidence also includes any exhibits that have been marked.

Evidence also may be used to prove a fact by inference; this is referred to as circumstantial evidence. In other words, from examining direct evidence you may be able to draw certain inferences which are reasonable and justified in light of your daily experience. Such inferences constitute circumstantial evidence. Circumstantial evidence may be given the same weight by you as direct evidence.

The evidence in this case consists of the sworn testimony of the witnesses, all of the exhibits received in evidence, any facts that the parties have agreed to or stipulated to, and any facts that I have instructed

you to find. You must consider all of the evidence, no matter which side produced or elicited it, because neither side has an exclusive right to the testimony of particular witnesses or to the evidence that is presented.

You should be mindful that any evidence which I have instructed you to consider for a limited purpose must be considered for that limited purpose only.

WHAT IS NOT EVIDENCE

Certain things are not evidence and cannot be considered by you as evidence. Arguments and statements by lawyers are not evidence. What they have said in their opening statements, closing arguments and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them differ from the way the lawyers have stated them, your memory controls. If the law as stated by the lawyers differs from the law as stated by the court, you must take the law from the court. You are not to be concerned with the wisdom of any rule of law stated by the court. Regardless of any opinion you may have as to what the law ought to be, it would be a violation of your sworn duty to base a verdict upon any other view of the law than that given in the instructions of the court, just as it would be a violation of your sworn duty, as judges of the facts, to base a verdict upon anything but the evidence in this case.

Questions and objections by lawyers are not evidence, unless the witness adopts the facts set forth in the question. Lawyers have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by objections or by my ruling on objections. It is the

responsibility of the court to rule on objections and the court has not intended to indicate in any way by its rulings or by what it has said what the verdict should be in this case. The court in this case, as in all cases, is completely neutral and impartial and leaves it to the jury to decide the case based on the facts as you find them to be and the law as the court will give it to you.

Testimony that has been excluded or stricken, or that you have been instructed to disregard, is not evidence and must not be considered. Anything you may have seen or heard when the court was not in session is not evidence. You are to decide the case solely on the evidence received at trial.

STIPULATIONS

A stipulation is an agreement between the parties as to the truth of a particular fact. If the parties have stipulated to a fact, you must consider that fact as having been proved.

JUDICIAL NOTICE

The court may take judicial notice of facts which I regard as common knowledge. By my taking judicial notice of these facts, neither party is required to introduce formal evidence to prove them. You must consider facts judicially noticed as having been proved. The significance of such facts to your ultimate findings in this case, however, is up to you to decide.

As a reminder, the court took judicial notice of certain Food & Drug Administration ("FDA") requirements for drug labels, which I will describe for you again later in these instructions. The court also took judicial notice that the National Drug Code ("NDC") number for Mutual Pharmaceutical Company's 200 mg sulindac tablets is 53489-*479-01.

BURDEN OF PROOF

In a civil case such as this, the party who makes a claim has the burden of proving that claim. This is referred to as the burden of proof. The party having the burden of proof must satisfy you that her claims on an issue are more probably so than not. This is referred to as proof by a preponderance of the evidence.

The party having the burden of proof does not have to prove her claims beyond a reasonable doubt as is required in a criminal case, nor does the party with the burden of proof have to prove her claims to a certainty. To meet the burden of proof, a party must prove that her claims are more probably so than not.

As an example, imagine in your mind the scales of justice. Put all the credible evidence on the scales, with the evidence in favor of the party having the burden of proof on one side of the scales and the evidence in favor of the other party on the other side. If the scales tip, ever so slightly, for the party having the burden of proof, then on that issue that party has sustained his burden. If the scales tip in favor of the other side, or remain in balance, then the burden of proof has not been satisfied.

CIVIL ACTION

As I explained to you at the beginning of the trial, this case is a civil action brought by the plaintiff, Karen Bartlett, against the defendant, Mutual Pharmaceutical Company (which I will sometimes refer to as "Mutual"). Mrs. Bartlett alleges that she took a generic prescription drug, known as sulindac, for pain in her shoulder, and that the drug caused her to suffer a condition known as Stevens-Johnson Syndrome ("SJS") and toxic epidermal necrolysis

("TEN"), which allegedly resulted in significant injuries. Mrs. Bartlett has brought a claim for strict products liability against Mutual, a manufacturer of the drug sulindac.

There can be occasions where a person is injured and another person or entity is legally responsible or liable, in which case the injured person is entitled to recover damages. There can also be occasions where a person is injured but no one is legally responsible or liable, in which case the injured person is not entitled to recover damages. Thus, it is important that you understand the particular legal claim that Mrs. Bartlett is making against Mutual in this case, which Mrs. Bartlett has the burden of proving by a preponderance of the evidence. I will now discuss the elements of that legal claim with you.

LIABILITY OF A CORPORATION

Before moving on to that discussion, however, I note that Mrs. Bartlett brought her claim against a corporation, Mutual Pharmaceutical Company. A corporation can be held liable to a plaintiff, just as an individual can.

The fact that the defendant is a corporation should play no other role in your deliberations, just as the fact that Mrs. Bartlett is an individual should play no role in your deliberations. All parties, whether individuals or corporations, have equal standing in the law.

STRICT LIABILITY CLAIM

As I just mentioned, Mrs. Bartlett has brought a claim against Mutual for strict products liability.

ELEMENTS OF CLAIM

In order to recover on her claim for strict products liability, Mrs. Bartlett must prove each of the following six elements by a preponderance of the evidence:

(1) That Mutual was in the business of selling sulindac;

(2) That sulindac's design was in a defective condition unreasonably dangerous to consumers;

(3) That the defective condition existed when Mutual sold the product;

(4) That the product reached Mrs. Bartlett without substantial change in the defective condition in which it was sold;

(5) That the purpose and manner of Mrs. Bartlett's use of sulindac was reasonably foreseeable by Mutual; and

(6) That the defective condition caused or substantially caused injury to Mrs. Bartlett.

BUSINESS OF SELLING PRODUCT

Mrs. Bartlett must prove that Mutual was in the business of selling sulindac. It is not necessary for Mrs. Bartlett to prove that Mutual sold sulindac directly to her or directly to the pharmacy that filled her prescription. It is sufficient if Mrs. Bartlett proves that Mutual placed sulindac into the stream of commerce.

DEFECT IN DESIGN

A defect in design occurs when the product has been manufactured in conformity with the manufacturer's design, but the design itself presents unreasonable danger to consumers.

Defective condition. In deciding whether sulindac's design presented unreasonable danger, you should consider the usefulness and desirability of the product to the public as a whole. A product is defective as designed if the magnitude of the danger outweighs the utility (or usefulness) of the product.

You should also consider whether sulindac's risk of danger, if any, could have been reduced without significant impact on the product's effectiveness or its manufacturing cost. Liability may exist if the manufacturer did not take available and reasonable steps to lessen or eliminate the danger of even a useful and desirable product.

Bear in mind that a manufacturer is not obliged to design the safest possible product, or a safer product, or one as safe as others make, so long as the design it has adopted is not unreasonably dangerous.

By the same token, you may find that a product's design was unreasonably dangerous even if the plaintiff has not presented evidence of an alternative design that could have made the product safer.

The warning. If you determine that sulindac was unreasonably dangerous, you may consider the presence and efficacy (or effectiveness) of a warning to avoid an unreasonable risk of danger from foreseeable uses of the product. The plaintiff must prove that the product was unreasonably dangerous even with its warning.

If you determine that sulindac was unreasonably dangerous and that a warning was not present and effective to avoid that unreasonable danger, then you must find that Mrs. Bartlett has proven this element of her claim (a defect in design). However, if you

determine that sulindac was unreasonably dangerous, but that a warning was present and effective to avoid that unreasonable danger, then you must find for Mutual.

FORESEEABLE USE

A manufacturer is not responsible for injuries caused by a product's defective condition unless the purpose and manner of the plaintiff's use of the product were reasonably foreseeable by the manufacturer. In terms of foreseeability, we are talking about reasonable foreseeability and not some sort of prophetic vision as to what might conceivably happen. A manufacturer may be held liable even if the user employs the product in an unintended but foreseeable manner.

CAUSATION

A product's defective condition is a legal cause of the plaintiff's injuries if it directly and in natural and continuous sequence produces or substantially contributes to producing the injuries, so that it can reasonably be said that, but for the defective condition, the injuries would not have occurred. In determining whether the defective condition was a legal cause of the plaintiff's injuries, you need not find that the defective condition was the sole cause of the injuries, but only that it was a substantial factor in bringing about the injuries, even though other factors may also have contributed to cause the injuries.

ADVERSE EVENT REPORTING RATES

You have heard testimony about the alleged number of adverse event reports of SJS/TEN associated with sulindac and other drugs, and about their alleged "reporting rates." In the context of this

trial, a "reporting rate" means the number of adverse event reports for a drug divided by the number of prescriptions for a drug. You should not confuse "reporting rate" with the rate at which SJS/TEN actually occurs with a drug. Those are two different concepts. You have not heard any testimony about the actual occurrence rate of SJS/TEN with sulindac individually, as compared with other individual drugs, except for those drugs that allegedly do not have any risk of SJS/TEN.

FDA APPROVAL

You have heard evidence that the Food and Drug Administration ("FDA") approved sulindac as safe and effective for its intended uses, that the FDA approved sulindac's label or "package insert" in place at the time of Mrs. Bartlett's prescription, and that the FDA required changes to that label and the labels of all other NSAIDs after the time of Bartlett's prescription. You may consider that evidence, along with all of the other evidence presented, in evaluating whether Mrs. Bartlett has proven her claim under the law as set forth in these instructions.

Neither the FDA's approval of the drug and its label, nor its requirement of label changes, is necessarily conclusive or controlling on any issue you have been asked to decide. You may give it as much or as little weight as you think it deserves, in light of all the evidence, under the law as set forth in these instructions.

FDA LABELING REQUIREMENTS

As I mentioned earlier, if you determine that sulindac was unreasonably dangerous, you may consider the presence and efficacy of a warning to

avoid an unreasonable risk of danger from foreseeable uses of the product. In evaluating that issue, you may consider the FDA's requirements for drug labels, along with all the other evidence presented. Compliance or non-compliance with FDA labeling requirements is not necessarily conclusive or controlling on that issue. You may give such evidence as much or as little weight as you think it deserves, in light of all the evidence.

As I instructed you during the trial, the court has taken judicial notice of the following FDA requirements for drug labels:

(1) The label must contain a summary of the essential scientific information needed for the safe and effective use of the drug.

(2) The label must be informative and accurate and neither promotional in tone nor false or misleading in any particular.

(3) The label's "Adverse Reactions" section must list the adverse reactions that occur with the drug and with drugs in the same pharmacologically active and chemically related class, if applicable. An adverse reaction is an undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence. In this listing, adverse reactions may be categorized by organ system, by severity of the reaction, by frequency, or by toxicological mechanism, or by a combination of these, as appropriate. If frequency information from adequate clinical studies is available, the categories and the adverse reactions within each category shall be listed in decreasing order of frequency. An adverse reaction that is significantly more severe than the

other reactions listed in a category, however, shall be listed before those reactions, regardless of its frequency.

(4) The label's "Warnings" section must describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. A serious adverse reaction is one that results in death, an immediate risk of death, inpatient hospitalization or prolongation of existing hospitalization, or a persistent or significant disability or incapacity. A disability is a substantial disruption of a person's ability to conduct normal life functions.

(5) The frequency of these serious adverse reactions and the approximate mortality and morbidity rates for patients experiencing the reaction, if known and important to safe and effective use of the drug, must be expressed as provided under the label's "Adverse Reactions" section.

The FDA also may require special problems, particularly those that may lead to death or serious injury, to be placed in a prominently displayed box on the drug label. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location will be specified by the FDA.

The FDA also may require that a drug label include a medication guide for patients, if the FDA determines that one or more of the following three circumstances exists:

(1) The drug is one for which patient labeling could help prevent serious adverse effects.

(2) The drug has serious risk, relative to benefits, of which patients should be made aware because information concerning the risk could affect patients' decisions to use, or to continue to use, the drug.

(3) The drug is important to health, and patient adherence to directions for use is crucial to the drug's effectiveness.

MEDICATION GUIDE

As I instructed you during the trial, a medication guide is designed and intended to provide information to patients about a prescription drug's side effects, if the FDA determines that such a guide is appropriate under the regulations that I just described for you.

In considering evidence regarding a medication guide, you should bear in mind that under New Hampshire law, which applies in this case, a prescription drug's warning is designed and intended for prescribing doctors, not for patients. Prescribing doctors decide what information they will read to educate themselves about the drugs they prescribe, and it is their decision whether or not to convey that information to their patients.

KNOWLEDGE AND CONDUCT NOT AT ISSUE

This claim is focused on the product sulindac, whether its design was in a defective condition unreasonably dangerous to consumers, and whether that defective condition caused Mrs. Bartlett's injuries. This claim is not about whether Mutual, Mrs. Bartlett, or the doctor who prescribed the drug knew of sulindac's safety risks, or any of their conduct in seeking or responding to such knowledge. Those issues

are not relevant to this case, and you should put them out of your mind.

DAMAGES

If you find that Mrs. Bartlett has sustained her burden of proving her claim for strict products liability, then the next step in your deliberations is to consider the issue of damages. However, if you find that Mrs. Bartlett has failed to prove her claim by a preponderance of the evidence, then you will conclude your deliberations. You must not compromise between the liability issue and the damage issue. You must determine the issue of liability first. You should proceed to the damage issue only if you have determined that Mutual's liability has been proven.

PROOF OF DAMAGES

Mrs. Bartlett has the burden of proving that it is more probable than not that the damages she seeks were caused by sulindac's defective condition. Mrs. Bartlett also has the burden of proving the nature and extent of her damages and the amount of money representing adequate compensation with such certainty as the nature of the claim and the circumstances permit.

COMPENSATORY DAMAGES

If you find that Mrs. Bartlett is entitled to damages in accordance with these instructions, then you should award a sum of money which will fairly compensate her for her injuries resulting from sulindac's defective condition. The award must be full, fair, and adequate. It must not be cheap or miserly, nor should it be a reward or prize. The purpose of the civil law is not to punish defendants for wrongdoing, but to compensate those who are injured in such amounts as the evidence

justifies. Damages should not be awarded out of sympathy, passion, or prejudice, nor should damages be based on guess or speculation. Damages must be based on the law and the evidence.

In determining the amount of damages to award Mrs. Bartlett, you may draw such inferences as are justified by your common experiences and observations of mankind, from the evidence of the nature of the injuries and the results thereof. You may also consider whether it is more probable than not that her damages will continue into the future as a direct, natural, and probable consequence of sulindac's defective condition and, if so, award her full, fair, and adequate compensation of those future damages.

ELEMENTS OF COMPENSATORY DAMAGES

In awarding damages, the following may be considered:

(1) The reasonable value of medical (hospital, nursing) care, services, and supplies reasonably required and actually given to date in the treatment of Mrs. Bartlett. The parties have stipulated that Mrs. Bartlett's past medical expenses as a result of her SJS/TEN are one million two hundred fifty thousand dollars ($1,250,000.00).

(2) The reasonable value of medical care, services, and supplies that will probably be required and given in the future treatment of Mrs. Bartlett.

(3) The present value of lost wages that Mrs. Bartlett probably would have earned to date, and probably would earn in the future, if she had not been injured. While there is no fixed rule to calculate the amount of damages to be recovered for loss of earning

capacity, you may consider evidence that tends to show that as a result of her injuries, the plaintiff's ability to earn money has been impaired or diminished.

(4) Reasonable compensation for pain and suffering experienced to date and which will probably be experienced in the future. This includes compensation for physical pain, discomfort, fears, anxiety, mental and emotional distress, and loss of enjoyment of life — that is, the inability to carry on and enjoy life in a way she would have had the accident not occurred.

There is no precise mathematical formula by which to fix reasonable compensation for pain and suffering. Nor is the opinion of any witness required as to the amount of such reasonable compensation. In making an award for pain and suffering, you should exercise your reasonable judgment. The damages you determine have to be full, fair, and adequate in light of the evidence.

LIFE EXPECTANCY TABLE

If you find from the evidence that Mrs. Bartlett is likely to continue to suffer damages in the future, you may consider her life expectancy, that is, the number of years she is likely to continue to suffer damages. According to a table of mortality, the life expectancy of a female aged 50.1 years is 32.6 additional years. This figure is not binding upon you. It is an estimate based on experience of persons who have reached that age. However, this figure may be considered by you in connection with other evidence relating to the probable life expectancy of Mrs. Bartlett, including evidence of her occupation, health, habits, and other activities, and circumstances bearing in mind that many persons live longer and many die sooner than the average.

NO PUNITIVE DAMAGES

The purpose of an award of damages is to compensate the plaintiff for her loss, not to punish the defendant. You are not permitted to award punitive damages or any other money damages for the purpose of punishing Mutual or making an example of it for the public good or for the purpose of preventing Mutual and others from similar conduct.

NO CONSIDERATION OF INSURANCE

During the trial, you heard Mutual's counsel ask some questions of witnesses about whether certain health plans and insurance companies have listed sulindac on a formulary or list of approved drugs. You may consider the testimony given in response to those questions only in evaluating whether sulindac's design was in a defective condition unreasonably dangerous to consumers.

You may not, however, consider the existence or non-existence of health insurance or any other kind of insurance coverage held by the parties in your determination of damages or any other issue in this case.

AMOUNT REQUESTED BY COUNSEL

If an amount of damages has been or is mentioned by Mrs. Bartlett's counsel, that is not evidence in this case. A specific request for a total dollar amount made by the plaintiff's counsel is simply a request for recovery. In the event you find for Mrs. Bartlett, the amount of the verdict must be based solely on the evidence presented during the course of the trial and the law which I have given to you.

MITIGATION OF DAMAGES

It is the duty of a person who has been injured to use reasonable effort without undue risk or expense (or humiliation) in caring for her injuries and reasonable means to prevent their aggravation and accomplish healing. When a person does not use reasonable effort to care for her own injuries, and those injuries are aggravated as a result of such failure, the responsibility of another who is legally liable or responsible for the original injury is limited to the amount of damage that would have been suffered had th . injured person herself exercised the effort required of her. You should not include in the verdict such damages, if any, that Mrs. Bartlett could have avoided by reasonable effort, without undue risk or expense.

VERDICT FORM

In the verdict form, the first question you will be asked is whether you find that Mrs. Bartlett has proven her claim for strict products liability by a preponderance of the evidence. If your answer to that question is no, you must conclude your deliberations. If your answer to that question is yes, you will then be asked how much compensatory damages you award to Mrs. Bartlett in each of the following categories, as I described them to you earlier in these instructions: (1) past medical expenses; (2) future medical expenses; (3) lost wages; and (4) pain, suffering, and loss of enjoyment of life.

CONCLUSION

The principles of law set forth in these instructions are intended to guide you in reaching a fair and just result in this case, which is important to the parties.

You are to exercise your judgment and common sense without prejudice, without sympathy, but with honesty and understanding. You should be conscientious in your determination of a just result in this case because that is your highest duty as officers of this court.

When you retire to the jury room, you should elect one member of the jury as your foreperson. That individual will act very much like the chairperson of a committee, seeing to it that the deliberations are conducted in an orderly fashion and that each juror has a full and fair opportunity to express his or her views, positions and arguments on the evidence and on the law.

The verdict must represent the considered judgment of each juror. In order to return a verdict, it is necessary that each juror agree thereto. Your verdict must be unanimous.

It is your duty as jurors to consult with one another and to deliberate with a view to reaching an agreement, if you can do so without violence to individual judgment. Each of you must decide the case for yourself, but do so only after an impartial consideration of the evidence in the case with the other jurors. In the course of your deliberations, do not hesitate to re-examine your own views and to change your opinion if convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of the evidence solely because of the opinion of the other jurors or merely for the purpose of returning

a verdict. You should also take as much time for deliberations in this case as you consider to be necessary and appropriate.

You were permitted to take notes during this trial, and I want to remind you of the instructions I gave you about your notes. Do not use your notes as authority to persuade other jurors. Your notes should be used only as aids to your own memory and must not be used as authority to persuade the other jurors of what the evidence was during the trial. You might have made an error or a mistake in recording what you have seen or heard. In the end, each juror must rely on his or her own recollection or impression as to what the evidence was. Your notes are not official transcripts of the testimony.

Remember at all times that you are not partisans, you are judges, judges of the facts. Your sole interest is to seek the truth from the evidence in the case. If during your deliberations it becomes necessary to communicate with the court, you may do so only in writing, signed by the foreperson or by one or more members of the jury. Give that note to the court security officer who will bring it to the court's attention. No member of the jury should ever attempt to communicate with the court except by a signed writing, and the court will communicate with the jury on anything concerning the case either in writing or orally in the courtroom. Remember that you are not to tell anyone, including the court, how the jury stands, numerically or otherwise, on the matters you are deciding, until after you have reached a unanimous verdict or have been discharged.

Nothing said in these instructions, or anything else I said during the trial, is intended to suggest or to

convey in any way or manner what your verdict should be. The verdict is the sole and exclusive duty and responsibility of the jury. The court is neutral and impartial in this matter and does not take sides.

When you have completed the verdict form according to these instructions and the instructions on the form, you will have concluded your deliberations and arrived at a verdict. At that point the foreperson should sign and date the verdict form. Then notify the security officer and you will be returned to the courtroom where the foreperson will render the verdict orally.

You may now retire to the jury room and commence your deliberations. I will see to it that the exhibits that were entered in the case are delivered to you.

Mutual Pharmaceutical Corporation
2002 Sulindac Package Insert (excerpts)

* * *

INDICATIONS AND USAGE

Sulindac is indicated for acute or long-term use in the relief of signs and symptoms of the following:

1. Osteoarthritis
2. Rheumatoid arthritis
3. Ankylosing spondylitis
4. Acute painful shoulder (Acute subacromial bursitis/supraspinatus tendinitis)
5. Acute gouty arthritis

* * *

WARNINGS

* * *

Hypersensitivity
Rarely, fever and other evidence of hypersensitivity (see ADVERSE REACTIONS) including ... severe skin reactions have occurred during therapy with sulindac. Fatalities have occurred in these patients. Hepatitis, jaundice, or both, with or without fever, may occur within the first one to three months of therapy. Determinations of liver function should be considered whenever a patient on therapy with sulindac develops unexplained fever, rash or other dermatologic reactions or constitutional symptoms. If unexplained fever or other evidence of hypersensitivity occurs, therapy with sulindac should be discontinued.

* * *

ADVERSE REACTIONS

* * *

Dermatologic
Stomatitis, sore or dry mucous membranes, alopecia, photosensitivity. Erythema multiforme, toxic epidermal necrolysis, Stevens-Johnson syndrome, and exfoliative dermatitis have been reported.

* * *

Hypersensitivity Reactions

* * *

A potentially fatal apparent hypersensitivity syndrome has been reported. This syndrome may include constitutional symptoms (fever, chills, diaphoresis, flushing), cutaneous findings (rash or other dermatologic reactions—see above), conjunctivitis, involvement of major organs (changes in liver function including hepatic failure, jaundice, pancreatitis, pneumonitis with or without pleural effision, leukopenia, leukocytosis, eosinophilia, disseminated intravascular coagulation, anemia, renal impairment, including renal failure), and other less specific findings (adenitis, arthralgia, arthritis, myalgia, fatigue, malaise, hypotension, chest pain, tachycardia).

* * *

Mutual Pharmaceutical Corporation
2007 Sulindac Package Insert (excerpts)

* * *

INDICATIONS AND USAGE

* * *

Sulindac is indicated for acute or long-term use in the relief of signs and symptoms of the following:

1. Osteoarthritis
2. Rheumatoid arthritis
3. Ankylosing spondylitis
4. Acute painful shoulder (Acute subacromial bursitis/supraspinatus tendinitis)
5. Acute gouty arthritis

* * *

Skin Reactions

NSAIDs, including sulindac tablets, can cause serious adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

* * *

ADVERSE REACTIONS

* * *

Dermatologic

Stomatitis, sore or dry mucous membranes, alopecia, photosensitivity. Erythema multiforme, toxic epidermal necrolysis, Stevens-Johnson syndrome, and exfoliative dermatitis have been reported.

* * *

Hypersensitivity Reactions

* * *

A potentially fatal apparent hypersensitivity syndrome has been reported. This syndrome may include constitutional symptoms (fever, chills, diaphoresis, flushing), cutaneous findings (rash or other dermatologic reactions—see above), conjunctivitis, involvement of major organs (changes in liver function including hepatic failure, jaundice, pancreatitis, pneumonitis with or without pleural effision, leukopenia, leukocytosis, eosinophilia, disseminated intravascular coagulation, anemia, renal impairment, including renal failure), and other less specific findings (adenitis, arthralgia, arthritis, myalgia, fatigue, malaise, hypotension, chest pain, tachycardia).

MEMORANDUM

DATE: April 6, 2005

FROM: John K. Jenkins, M.D.
Director, Office of New Drugs (OND)
and
Paul J. Seligman, M.D., M.P.H
Director, Office of
Pharmacoepidemiology and Statistical
Science (OPaSS)

THROUGH: Steven Galson, M.D., M.P.H.
Acting Director, Center for Drug
Evaluation and Research

TO: NDA files 20-998, 21-156, 21-341, 21-042

SUBJECT: Analysis and recommendations for Agency action regarding non- steroidal anti-inflammatory drugs and cardiovascular risk

Executive Summary

Following a thorough review of the available data we have reached the following conclusions regarding currently approved COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs)[1] and the risk of adverse cardiovascular (CV) events:[2]

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[1] A list of the non-selective NSAIDs is available on http://www.fda.gov/cder/drug/infopage/cox2/default.htm.

[2] The degree of COX-2 selectivity for any given drug has not been definitively established, and there is considerable overlap in *in-vitro* COX-2 selectivity between agents that have been generally considered to be COX-2 selective (e.g., celecoxib, rofecoxib, valdecoxib, parecoxib, lumiracoxib, etoricoxib) and older NSAIDs

- The three approved COX-2 selective NSAIDs (i.e., celecoxib, rofecoxib, and valdecoxib) are associated with an increased risk of serious adverse CV events compared to placebo. The available data do not permit a rank ordering of these drugs with regard to CV risk.
- Data from large long-term controlled clinical trials that have included a comparison of COX-2 selective and non-selective NSAIDs do not clearly demonstrate that the COX-2 selective agents confer a greater risk of serious adverse CV events than non- selective NSAIDs.
- Long-term placebo-controlled clinical trial data are not available to adequately assess the potential for the non-selective NSAIDs to increase the risk of serious adverse CV events.
- Pending the availability of additional long-term controlled clinical trial data, the available data are best interpreted as being consistent with a class effect of an increased risk of serious adverse CV events for COX-2 selective and non-selective NSAIDs.
- Short-term use of NSAIDs to relieve acute pain, particularly at low doses, does not appear to confer an increased risk of serious adverse CV events (with the exception of valdecoxib in hospitalized patients immediately post-

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that have been considered to be non-selective (e.g., diclofenac, ibuprofen, naproxen). For purposes of simplicity of discussion and comparisons, this document maintains the traditional separation between COX-2 selective and non-selective agents, but our use of this nomenclature should not be considered as FDA endorsement of such designations.

operative from coronary artery bypass (CABG) surgery).

- Controlled clinical trial data are not available to rigorously evaluate whether certain patients derive greater relief of pain and inflammation from specific NSAIDs compared to others or after failing to respond to other NSAIDs.
- The three approved COX-2 selective drugs reduce the incidence of GI ulcers visualized at endoscopy compared to certain non-selective NSAIDs. Only rofecoxib has been shown to reduce the risk of serious GI bleeding compared to a non-selective NSAID (naproxen) following chronic use. The overall benefit of COX-2 selective drugs in reducing the risk of serious GI bleeding remains uncertain, as does the comparative effectiveness of COX-2 selective NSAIDs and other strategies for reducing the risk of GI bleeding following chronic NSAID use (e.g., concomitant use of a non-selective NSAID and a proton pump inhibitor).
- Valdecoxib is associated with an increased rate of serious and potentially life- threatening skin reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) compared to other COX-2 selective agents and is the only NSAID with a boxed warning for this adverse event in its approved package insert. In the absence of any demonstrated advantage over other NSAIDs, the overall benefit versus risk profile for valdecoxib is unfavorable for marketing.

Based on these conclusions, we recommend the following regulatory actions to further improve the safe

and effective use of these drugs by prescribers, patients, and consumers:

- The agency should ask Pfizer to voluntarily withdraw Bextra (valdecoxib) from the U.S. market. In the event Pfizer does not agree to a voluntary withdrawal, the agency should initiate the formal withdrawal procedures; i.e., issuance of a Notice of Opportunity for Hearing (NOOH).
- The professional labeling for all prescription NSAIDs should be revised to include a boxed warning highlighting the potential increased risk of serious adverse CV events. The boxed warning should also include the well described NSAID class risk of serious, and often life-threatening, GI bleeding, which is currently contained in a bolded warning.
- Pending the availability of additional data, the labeling for all prescription NSAIDs should include a contraindication for use in patients immediately post-operative from CABG surgery.
- A class NSAID Medication Guide should be developed to inform patients of the potential increased risk of serious adverse CV events and the risk of serious GI bleeding.
- The labeling for non-prescription NSAIDs should be revised to include more specific information about potential CV and GI risks and information to assist consumers in the safe use of these drugs.
- The boxed warning for Celebrex (celecoxib) should specifically reference the available data that demonstrate an increased risk of serious

adverse CV events and other sections of the labeling should be revised to clearly reflect these data.

- The agency should carefully review any proposal from Merck for resumption of marketing of Vioxx (rofecoxib). We recommend that such a proposal be reviewed by the FDA Drug Safety Oversight Board and an advisory committee before a final decision is reached.
- The agency should request that all sponsors of non-selective NSAIDs conduct and submit for FDA review a comprehensive review and analysis of available controlled clinical trial databases to further evaluate the potential for increased CV risk.
- The agency should work closely with sponsors and other interested stakeholders (e.g., NIH) to encourage additional long-term controlled clinical trials of non-selective NSAIDs to further evaluate the potential for increased CV risk.

Background

Vioxx (rofecoxib) was voluntarily withdrawn from the market by Merck in September 2004 following the observation of an increased risk of serious adverse CV events compared to placebo in a long-term controlled clinical trial. Subsequent to that action, reports of additional data from controlled clinical trials became available for other COX-2 selective NSAIDs that also demonstrated an increased risk of serious adverse CV events compared to placebo. These new data prompted the agency to conduct a comprehensive review of the available data and to present the issue for review at a joint meeting of FDA's Arthritis and Drug Safety and

Risk Management Advisory Committees on February 16-18, 2005.

Following the joint meeting, CDER conducted a thorough internal review of the available data regarding cardiovascular (CV) safety issues for COX-2 selective and non-selective non- steroidal anti-inflammatory drugs (NSAIDs). This memorandum summarizes the major issues considered in that review, our conclusions regarding the interpretation of the available data, and our recommendations for regulatory actions necessary to further improve the safe and effective use of these drugs by prescribers, patients, and consumers.

Participants in the CDER review included staff from the Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products, the Division of Over-the-Counter Drug Products, the Offices of Drug Evaluation II and V, the Office of New Drugs, the Office of Drug Safety, the Office of Biostatistics, the Office of Pharmacoepidemiology and Statistical Science, the Office of Medical Policy, the Office of Regulatory Policy, and the Office of the Center Director. Materials reviewed included the regulatory histories and the NDA and postmarketing databases of the various NSAIDs, FDA and sponsor background documents prepared for the Advisory Committee meeting, all materials and data submitted by other stakeholders to the Advisory Committee meeting, presentations made at the Advisory Committee meeting, the discussions held by the Committee members during the meeting, and the specific votes and recommendations made by the joint Committee.

Summary of available data

The most persuasive evidence in support of an increased risk of serious adverse CV effects of the COX-2 selective NSAIDs is derived from a small number of long-term placebo- and active-controlled clinical trials in patients with arthritis or in the disease prevention setting. We will briefly summarize the available data from the long-term controlled clinical trials for the three approved and two investigational COX-2 selective agents. We will also briefly summarize the available data from long-term controlled clinical trials to assess the potential for increased CV risk for the non-selective NSAIDs. Finally, we will briefly summarize the available data from observational studies that have sought to assess the potential for increased CV risk for NSAIDs. We will focus our discussion on the combined endpoint of death from CV causes, myocardial infarction (MI), and stroke, as that is a widely accepted endpoint in assessing the benefits and risks of a drug for CV outcomes. It should be noted that the exact definitions and adjudication procedures for this combined endpoint vary to some degree across the trials discussed below.

Celecoxib

The strongest data in support of an increased risk of serious adverse CV events for celecoxib comes from the National Cancer Institute's Adenoma Prevention with Celecoxib (APC) trial in patients at risk for recurrent colon polyps. In the APC trial a 2-3 fold increased risk of adverse CV events was seen for celecoxib compared to placebo after a mean duration of treatment of 33 months. There was evidence of a dose

response relationship, with a hazard ratio[3] of 2.5 for celecoxib 200 mg twice daily and 3.4 for celecoxib 400 mg twice daily compared to placebo for the composite endpoint of death from CV causes, myocardial infarction (MI), or stroke.

The results from the APC trial were not replicated, however, in the nearly identical Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial. Based on preliminary, unpublished data presented by the PreSAP investigators at the AC meeting, the hazard ratio was 1.1 for celecoxib 400 mg once daily compared to placebo for the composite endpoint of death from CV causes, MI, or stroke. It is worth noting that the dosing interval differed between the APC trial (twice daily) and the PreSAP trial (once daily), although both trials included a total daily dose of celecoxib of 400 mg. It remains unclear what, if any, role this difference in dosing interval may have played in the disparate findings between the two trials.

Another long-term controlled clinical trial of celecoxib versus placebo, the National Institute of Aging's Alzheimer's Disease Anti-Inflammatory Prevention Trial (ADAPT) in patients at risk for Alzheimer's disease, also does not appear to have shown an increased risk for celecoxib 200 mg twice daily compared to placebo for the composite endpoint of death, MI, or stroke. Preliminary, unpublished data shared with FDA by the ADAPT investigators showed no increased relative risk for celecoxib compared to

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[3] The hazard rate is a measure of risk per unit of time in an exposed cohort (e.g., the event rate per month). The hazard ratio is the ratio of the hazard rates from the treatment group relative to the control group, and is often used to represent the relative risk when the relative risk is constant over time.

placebo.[4] Finally, there was a small one-year trial comparing celecoxib 200 mg twice daily to placebo in patients with Alzheimer's disease that did not demonstrate a significantly increased risk of serious adverse CV events, but did show a trend toward more CV events in the celecoxib treatment arm.

The only available data from a long-term comparison of celecoxib to non-selective NSAIDs come from the Celebrex Long-Term Arthritis Safety Study (CLASS) in which celecoxib 400 mg twice daily was compared to diclofenac and ibuprofen in approximately 8000 patients with osteoarthritis or rheumatoid arthritis. No differences were observed for serious adverse CV events between celecoxib and the two non-selective NSAID comparators in this trial.

The ADAPT trial also included naproxen as an active control and will provide an additional comparison of celecoxib to a non-selective NSAID when the final study results become available. Preliminary, unpublished data shared with FDA by the ADAPT investigators showed that celecoxib was intermediate between placebo (lowest incidence) and naproxen (highest incidence) for the composite endpoint of death, MI, or stroke.

Rofecoxib

The strongest data from a long-term placebo-controlled trial for an increased risk of serious adverse CV events with rofecoxib come from the Adenomatous

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[4] Relative risk is defined as the cumulative risk in the treatment group (e.g., number of events per the number of individuals in this group) divided by the cumulative risk in the control group. The term relative risk is often used interchangeably with the hazard ratio.

Polyp Prevention on Vioxx (APPROVe) trial in which rofecoxib 25 mg once daily was compared to placebo for up to three years. A relative risk of approximately two was seen for rofecoxib compared to placebo for serious adverse CV events. It is noteworthy that the rofecoxib and placebo CV event curves in a Kaplan-Meier plot did not appear to begin to separate until after approximately 18 months of treatment. In contrast to the results seen in APPROVe, two long-term placebo-controlled trials in patients with early Alzheimer's disease, including up to four years of treatment in a small number of patients, did not show a significant difference in CV events between rofecoxib 25 mg once daily and placebo.

The only long-term controlled clinical trial comparison of rofecoxib to a non-selective NSAID comes from the Vioxx GI Outcomes Research (VIGOR) trial in which rofecoxib 50 mg once daily was compared to naproxen for up to 12 months. In VIGOR, rofecoxib was associated with a hazard ratio of approximately two compared to naproxen based on the composite endpoint of death, MI, or stroke. In contrast to the findings in APPROVe, in VIGOR the Kaplan-Meier CV event curves for rofecoxib and naproxen began to separate after approximately two months of treatment.

Valdecoxib

No long-term controlled clinical trials have been conducted comparing valdecoxib to either placebo or non-selective NSAIDs. Data are available from two short-term placebo- controlled trials of early dosing with intravenous parecoxib (a pro-drug for valdecoxib) followed by oral valdecoxib in patients immediately post-operative from coronary artery bypass graft (CABG) surgery. In both studies, valdecoxib was

associated with an approximately two-fold increased risk of serious adverse CV events compared to placebo. In contrast, a short-term placebo-controlled trial of intravenous parecoxib followed by oral valdecoxib in patients undergoing various types of non-vascular general surgical procedures showed no differences for serious adverse CV events.

Investigational COX-2 Selective Agents

Data from long-term controlled clinical trials are also available for two investigational COX-2 selective agents (lumiracoxib and etoricoxib), and were presented at the AC meeting. These data are summarized here as they provide further insights regarding the issue of CV risk for COX-2 selective agents and the comparison of CV risks between COX-2 selective drugs and non-selective NSAIDs.

The Therapeutic COX-189 Arthritis Research and Gastrointestinal Event Trial (TARGET) compared lumiracoxib 400 mg once daily to naproxen and ibuprofen for one year in approximately 18,000 patients with osteoarthritis. TARGET was designed as two sub- studies and the planned primary analysis was to be the combined lumiracoxib groups compared to the combined naproxen and ibuprofen groups. The study design, however, did not clearly reflect this intent since randomization occurred at the sub-study level rather than across the entire study. For reasons that are not entirely clear, but possibly related in part to the randomization schema, the event rates for serious adverse CV events in the lumiracoxib groups in the two sub-studies were very different, i.e., 1.1 events per 100 patient years in the naproxen sub-study versus 0.58 events per 100 patient years in the ibuprofen sub-study. The event rates for serious adverse CV events

for naproxen and ibuprofen were very similar in the two sub-studies; i.e., 0.76 events per 100 patient years for naproxen and 0.74 events per 100 patient years for ibuprofen.

The pre-specified primary analysis of TARGET found no difference in serious adverse CV events between the combined lumiracoxib groups and the combined naproxen and ibuprofen groups. The validity of combining the two lumiracoxib groups for purposes of the primary analysis is debatable, however, given the study design and the very different lumiracoxib event rates in the two sub-studies. It is unfortunate that the study design did not call for randomization of treatment assignment across the entire study, which would have allowed for a much more powerful comparison of lumiracoxib to the two non-selective NSAIDs.

Given the study design, the data from TARGET have also been analyzed by sub-study. In the naproxen sub-study, a hazard ratio of 1.44 was observed for the comparison of lumiracoxib and naproxen for serious adverse CV events. In the ibuprofen sub-study, a hazard ratio of 0.79 was observed for the comparison of lumiracoxib and ibuprofen for serious adverse CV events. The observed differences between lumiracoxib and the NSAID comparators were not statistically significantly different in either sub-study.

Depending on which analysis of the TARGET study one considers, the conclusions may be very different. The pre-specified primary analysis would suggest that lumiracoxib, a highly COX-2 selective agent, is indistinguishable from two non-selective agents with regard to the risk of serious adverse CV effects. The sub-study results, however, would suggest that

lumiracoxib may be associated with a slightly increased CV risk compared to naproxen and a slightly decreased CV risk compared to ibuprofen. The cross sub-study comparison of naproxen and ibuprofen, however, would suggest no difference in CV risk for these non- selective NSAIDs. Overall, this study does not support a clear distinction between lumiracoxib and the non-selective NSAIDs.

The Etoricoxib versus Diclofenac Sodium Gastrointestinal Tolerability and Effectiveness Trial (EDGE) compared etoricoxib 90 mg once daily versus diclofenac for up to 16 months in approximately 7100 patients with osteoarthritis. The relative risk for serious adverse CV events was 1.07 for the comparison of etoricoxib to diclofenac (not significantly different). EDGE, therefore, is another large controlled clinical trial that did not distinguish COX-2 selective and non-selective NSAIDs with regard to CV risk.

Non-selective NSAIDs

Long-term placebo- and active-controlled trials are generally not available for the non- selective NSAIDs, with the exception of the studies noted above where certain non-selective NSAIDs were used as active controls in studies of COX-2 selective drugs.

Observational studies

Data are available from a number of published and unpublished observational studies to address the issue of increased risk of serious adverse CV events for COX-2 selective and non-selective NSAIDs. These studies have utilized a variety of designs, methods, source databases, and comparison groups, and each study has been characterized by strengths and weaknesses. In most of the observational studies, the estimated

relative risks of the COX-2 selective NSAIDs have ranged from 0.8 to 1.5, with many point estimates not achieving statistical significance. These data were presented and discussed in detail at the AC meeting and the committee members generally agreed that the observational data could not definitively address the question of a modestly increased CV risk for the COX-2 selective compared to the non-selective NSAIDs, with the possible exception of data on rofecoxib 50 mg.

Overall, the most consistent finding for increased CV risk was observed for rofecoxib 50 mg, where statistically significant relative risks of approximately 2 and 3 were seen in two studies. The signal for increased CV risk for the 25 mg rofecoxib dose, however, was smaller and did not consistently achieve statistical significance. The relative risks in the seven observational studies for celecoxib ranged from 0.4 to 1.2, with statistical significance observed once for a lowered risk and once for a higher relative risk. The available data for the non-selective NSAIDs from the observational studies are limited, and no consistent signals were observed.

Analysis and Conclusions

As noted above, the most persuasive evidence in support of an increased risk of serious adverse CV effects of the COX-2 selective NSAIDs is derived from a small number of long- term placebo- and active-controlled clinical trials in patients with arthritis or in the disease prevention setting. The data from these trials, however, are not consistent in demonstrating an increased risk of serious adverse CV effects for COX-2 selective drugs. Perfect replication of study results cannot be expected, and is not required to reach a valid scientific conclusion. However, the degree of

inconsistency observed in the data from long-term controlled clinical trials has a considerable impact on our ability to reach valid conclusions about the absolute magnitude of increased risk and to make risk versus benefit determinations for particular doses of specific drugs.

The data from controlled clinical trial comparisons of COX-2 selective and non-selective NSAIDs do not clearly demonstrate an increased relative risk for the COX-2 selective drugs, despite the substantial size of these studies. Only VIGOR clearly indicates such a difference with CLASS and EDGE giving no suggestion of a difference and TARGET giving analysis-dependent results. These findings, and the absence of any long-term placebo- or active- controlled clinical trials for most of the non-selective NSAIDs, make it difficult to conclude that the COX-2 selective drugs as a class have greater CV risks than non-selective NSAIDs. The data from the well-controlled observational trials also have not provided consistent assessments of risk when comparing COX-2 selective and non-selective NSAIDs. The point estimates of the relative risk comparisons from these data are mostly in a range where interpretation may be difficult and influenced by uncontrolled residual confounding or biases often inherent in the design and data limitations of these studies

Despite the limitations of the available data, overall, there is evidence, principally from a small number of placebo-controlled trials, that the approved COX-2 selective NSAIDs (i.e., celecoxib, rofecoxib, valdecoxib) are associated with an increased risk of serious adverse CV events (e.g., MI, stroke, and death). It remains unclear, however, that it is the presence of,

or the degree of, COX-2 selectivity that accounts for these observations, as some have hypothesized. As noted above, in various controlled clinical trials, COX-2 selective drugs have been indistinguishable from non-selective NSAIDs (i.e., ibuprofen, diclofenac) in studies of substantial size and duration. Further, although on theoretical grounds the addition of low-dose aspirin (a COX-1 inhibitor) to a COX-2 selective drug should resolve any increased CV risk caused by COX-2 selectivity, this effect has not in fact been observed in several studies in which such comparisons are possible. Taken together, these observations raise serious questions about the so called "COX-2 hypothesis," which suggests that COX-2 selectivity contributes to increased CV risk. It, therefore, remains unclear to what extent the COX-2 selectivity of an individual drug predicts the drug's potential for an increased risk of adverse CV events compared to drugs that are less COX-2 selective.

After carefully reviewing all the available data, we believe that the data are sufficient to support a conclusion that celecoxib, rofecoxib, and valdecoxib are associated with an increased risk of serious adverse CV events when compared to placebo. For celecoxib and rofecoxib these conclusions are primarily supported by the data from the APC and APPROVe trials, respectively. However, for celecoxib a nearly identical long-term placebo- controlled trial (the PreSAP trial) and a similarly sized placebo-controlled trial in patients at increased risk for Alzheimer's disease did not replicate these findings. For rofecoxib, other long-term placebo-controlled trials of equal or greater duration (the Alzheimer's treatment trials) did not replicate the APPROVe findings. There are no long-term placebo-controlled trial data for valdecoxib. It is

difficult to know how to extrapolate the findings from the parecoxib/valdecoxib CABG trials to the chronic use situation given the significant physiologic and traumatic impact on the coronary vasculature during and following CABG surgery, and the systemic pro-inflammatory response resulting from heart-lung bypass. We believe, however, that it is reasonable from a public health perspective to assume that valdecoxib does not differ from the other COX-2 selective agents with regard to increased CV risk with chronic use pending the availability of data from long-term controlled clinical trials that would indicate otherwise.

The long-term controlled clinical trial data comparing COX-2 selective agents (i.e., celecoxib, rofecoxib, lumiracoxib, etoricoxib) to non-selective NSAIDs are limited in number, but include several trials of very substantial size. They raise significant unresolved questions. First, rofecoxib 50 mg clearly appears to have an increased risk of serious adverse CV events compared to naproxen based on the data from the VIGOR trial.[5] The absence of a placebo arm in the VIGOR trial, however, precludes a determination of whether chronic use of naproxen might also confer an increased risk of serious adverse CV events, albeit at a lower rate than rofecoxib. The VIGOR trial also does not provide a comparison between lower doses of rofecoxib and naproxen. Other controlled clinical trial data have also suggested some increased risk of serious adverse CV events for COX-2 selective agents versus naproxen (i.e., lumiracoxib in

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[5] Rofecoxib 50 mg is not recommended for chronic use in the approved labeling for Vioxx. The higher dose of rofecoxib was used in the VIGOR trial to provide a "worst case" estimate of the risk of serious GI bleeding for rofecoxib in comparison to naproxen.

the naproxen sub-study in TARGET and etoricoxib in the NDA database); however, these studies also leave unresolved the question of whether naproxen is itself associated with an increased CV risk. The ADAPT trial is the only long-term controlled clinical trial in which a COX-2 selective agent and naproxen have been compared to placebo. The preliminary data from the ADAPT trial, however, do not appear to follow the pattern of the other COX-2 selective versus naproxen trials, showing a trend toward a higher event rate on naproxen compared to celecoxib and placebo (see above). Further, the cross sub-study comparison of naproxen and ibuprofen in TARGET suggests no difference in CV risk between these two non-selective NSAIDs. Taken together these data provide some support for the conclusion that a difference exits in the risk of serious adverse CV events between COX-2 selective agents and naproxen, but they do not provide any assurance that naproxen itself confers no increased CV risk; i.e., we cannot consider naproxen to be equal to or better than placebo.

The comparisons of COX-2 selective agents to certain other non-selective NSAIDs also raise interesting, and in the end unresolved, questions regarding the relative risk of COX-2 selective drugs compared to non-selective NSAIDs, despite the very large size of some of the trials. Several long-term controlled clinical trial comparisons of COX-2 selective agents to diclofenac have failed to provide evidence that diclofenac has a lower risk of serious adverse CV events than COX-2 selective agents (e.g., versus celecoxib in CLASS, versus etoricoxib in the NDA database, versus etoricoxib in EDGE). Large, long-term controlled clinical trial comparisons of COX-2 selective agents to ibuprofen, an unequivocally non-

selective agent, also have failed to suggest a clear separation with regard to the risk of serious adverse CV events (e.g., versus celecoxib in CLASS, versus lumiracoxib in the ibuprofen sub-study in TARGET). While even these large studies cannot rule out a small true difference in CV risk between COX-2 selective agents and diclofenac and ibuprofen, they show no clear trend and are best interpreted as showing that the risk of serious adverse CV events between COX-2 selective agents and either diclofenac and ibuprofen are in fact very similar. The latter interpretation, taken together with the findings of an increased risk of serious adverse CV events from the long-term placebo-controlled clinical trials of COX-2 selective agents, would support a conclusion that at least some of the non-selective NSAIDs are also associated with an increased risk of serious adverse CV events.

The inability to reliably estimate the absolute magnitude of the increased risk of serious adverse CV events for individual COX-2 agents, combined with the inability to reliably draw conclusions about the risk of COX-2 agents compared to one another or to other NSAIDs, highlights the conundrum the Agency faces in making decisions on appropriate regulatory actions. There is an urgent public health need to make appropriate regulatory decisions because the adverse events at issue are serious and a very large number of patients use selective and non-selective NSAIDs to treat chronic pain and inflammation. At the same time, erroneous conclusions and inappropriate actions are themselves potentially harmful to the public health. Although the currently available data are not definitive, the Agency cannot await more definitive data, which may take years to accumulate from studies that have not even begun, before taking action.

In summary, we conclude that the three approved COX-2 selective drugs are associated with an increased risk of serious adverse CV events, at least at some dose, with reasonably prolonged use. We do not believe, however, that the currently available data allow for a rank ordering of the approved COX-2 selective drugs with regard to CV risk. We also believe that it is not possible to conclude at this point that the COX-2 selective drugs confer an increased risk over non-selective NSAIDs in chronic use. Naproxen may be an exception, but the comparative data to COX-2 selective agents are not entirely consistent, we do not have adequate long-term placebo-controlled data to fully assess its potential CV risks, and the cross sub-study comparison to ibuprofen in TARGET does not suggest a lesser CV risk. For the vast majority of non-selective NSAIDs we do not have any data that allow comparisons with COX-2 selective agents for CV risk, and where data exist, primarily from very large studies, they do not consistently demonstrate that the COX-2 agents confer a greater risk. Finally, there are no data from long-term placebo-controlled trials for the non- selective NSAIDs (other than the preliminary data for naproxen from ADAPT) that are analogous to the data available for the COX-2 selective agents.

The absence of long-term controlled clinical trial data for the non-selective NSAIDs significantly limits our ability to assess whether these drugs may also increase the risk of serious adverse CV events. The long marketing history of many of these drugs cannot be taken as evidence that they are not associated with an increased risk of serious adverse CV events since CV events occur fairly commonly in the general population and small increases in common adverse events are impossible to detect from spontaneous

reporting systems. The adverse CV risk signal for the COX-2 selective drugs became apparent only from large, long-term controlled clinical trials and large retrospective cohort studies. Similar clinical trials are needed to assess the potential risks of the non-selective NSAIDs.

Given our inability to conclude, based on the available data, that the COX-2 selective agents confer an increased risk of serious adverse CV events compared to non-selective NSAIDs, we believe that it is reasonable to conclude that there is a "class effect" for increased CV risk for all NSAIDs pending the availability of data from long-term controlled clinical trials that more clearly delineate the true relationships. This interpretation of the available data will serve to promote public health by alerting physicians and patients to this class concern and will make it clear that simply switching from a COX-2 selective agent to a non-selective NSAID does not mean that the potential for increased risk of serious adverse CV events has been fully, or even partially, mitigated.

With a "class effect" of NSAIDs on CV risk as a baseline, other factors must be considered in determining the overall risk versus benefit profile for individual drugs within the class and what, if any, regulatory actions are appropriate. Some of the factors that must be considered include any demonstrated benefit of a given drug over other drugs in the class (e.g., superiority claims, effectiveness in patients who have failed on other drugs) and any unique toxicities (or absence of a toxicity) of a given drug over other drugs in the class.

With regard to greater or special effectiveness, while it is widely believed that patients differ in their response to NSAIDs, there are no controlled clinical trial data (e.g., studies in non- responders to a particular NSAID) to support such conclusions. Nonetheless, despite the lack of rigorous evidence, this widely accepted belief is at least in part a valid rationale for maintaining a range of options in the NSAID class from which physicians and patients may choose. In addition, as noted above, there is no basis for concluding that the risk of serious adverse CV events for some NSAIDs is worse than the risk for the others, which supports maintaining a range of options.

With regard to toxicities, the primary goal in developing COX-2 selective agents was to reduce the serious, and often life-threatening, risk of gastrointestinal (GI) bleeding associated with chronic use of all NSAIDs. To date, the only COX-2 selective agent that has demonstrated a reduced risk for serious GI bleeding is rofecoxib, but only in comparison to naproxen. All of the approved COX-2 selective agents have been shown to reduce the incidence of GI ulcers visualized at endoscopy compared to certain non-selective NSAIDs, but the clinical relevance of this finding as a predictor of serious GI bleeding has not been confirmed (e.g., no difference in serious GI bleeding was observed in CLASS). Improved GI tolerability of NSAIDs is an important issue from an individual patient and public health perspective and is, at least in part, a valid rationale for maintaining a range of options in the NSAID class from which physicians and patients may choose. Besides the COX-2 selective NSAIDs, other strategies are available that may reduce the risk of GI bleeding with NSAIDs (e.g., combined use of a non-selective NSAID with

misoprostol or a proton pump inhibitor), but data are currently lacking on how these strategies compare to the use of COX-2 selective drugs. With the exception of the comparison of rofecoxib to naproxen, data are not available to confirm a reduced risk of serious GI bleeding for the COX-2 selective agents, though it is widely believed that these agents are better tolerated by many patients.

In addition to the risk of serious and potentially life-threatening GI bleeding, NSAIDs are also associated with other potentially serious adverse effects, including, but not limited to, fluid retention, edema, renal toxicity, hepatic enzyme elevation, and bronchospasm in patients with aspirin-sensitive asthma. Comparative data to differentiate NSAIDs from one another with regard to these adverse effects are generally not available or are inconclusive.

Boxed warnings are currently included in the approved labeling for two single ingredient NSAID products.[6] Bextra (valdecoxib) has a boxed warning for serious and potentially life- threatening skin reactions (i.e., toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme). Toradol (ketorolac) has a boxed warning emphasizing that it is approved only for short-term (≤5 days) use in patients with moderately severe acute pain that requires analgesia at the opioid level, usually in a post-operative setting. Toradol is the only NSAID indicated for treatment of pain available for parenteral use (i.e., IV or IM injection); it therefore provides an important therapeutic option for physicians and patients in

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[6] The package insert for Arthrotec, a combination of diclofenac and misoprostol, includes a boxed warning, but the warning relates to potential toxicities of misoprostol, not diclofenac.

settings where the patient cannot take analgesics by mouth.[7] This therapeutic advantage favors continued availability of Toradol, despite the need for a boxed warning about the potential for increased frequency of serious adverse reactions with long-term (≥5 days) use. In contrast, there are no data to support a unique therapeutic benefit for Bextra over other available NSAIDs, which might offset the increased risk of serious and potentially life- threatening skin reactions. While other COX-2 selective and non-selective NSAIDs also have a risk for these rare, serious skin reactions, the reported rate for these serious side effects appears to be greater for Bextra than for other COX-2 agents.[8] To date, the agency has received 7 reports of deaths from serious skin reactions in patients following treatment with Bextra. The occurrence of these serious skin reactions in individual patients is unpredictable, occurring with and without a

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[7] Indomethacin is also available as a parenteral formulation, but is only indicated for parenteral use for treatment of patent ductus arteriosus.

[8] The agency has recently received a Citizens Petition regarding the risk of Stevens-Johnson syndrome with ibuprofen (February 15, 2005). Although the petition is currently under review, and the agency has not reached a decision on the requested actions, based on analyses of data obtained before the petition was submitted, the agency has determined that the labeling for non-prescription NSAIDs should be updated to warn of the potential for skin reactions. Accordingly, along with the changes to the label to address CV risks, the agency will ask manufacturers of non-prescription NSAIDs to make these changes. After we have completed our review of the petition, we may determine that additional labeling changes with regard to potential skin reactions are warranted. The risk for serious skin reactions is already included in the labeling for most prescription NSAIDs.

history of sulfa allergy (valdecoxib is a sulfonamide) and after both short- and long-term use, which makes attempts to manage this increased risk difficult.

Several non-selective NSAIDs are currently available to consumers without a prescription (e.g., ibuprofen, naproxen, ketoprofen). The non-prescription doses of these products are generally well below the maximum daily prescription doses for the same active ingredient and the duration of treatment without specific alternate instructions from a physician is limited to 10 to 14 days. The applicability of the increased risk of serious adverse CV events as described above from controlled clinical trials to low-dose, short-term use of these non-prescription products for the relief of acute pain is unclear, although any such risk is expected to be minimal. No signal for increased risk of serious adverse CV events has been detected in the short-term controlled clinical trials that supported the approval of these agents for treatment of acute pain. While these studies were primarily designed to evaluate effectiveness, the absence of a signal of increased CV risk provides some reassurance of the safety of short-term use. Further, with the exception of the parecoxib/valdecoxib CABG studies, the increased risk of serious adverse CV events in the controlled clinical trials described above have only become apparent after months to years of treatment. The parecoxib/valdecoxib data also provide support for the safety of short-term use. The two short-term placebo-controlled CABG studies showed an increased risk of serious CV events, but, a short-term placebo-controlled trial in general surgery patients did not show an increased risk. These data may suggest that in the absence of a predisposing condition, such as recent CABG surgery, the CV risk of short-term use of

NSAIDs is very small, if any, particularly at low doses and given the typically intermittent nature of use of non- prescription NSAIDs for relief of acute pain.

Aspirin is also an NSAID that is available and widely used without a prescription. However, aspirin has other unique pharmacologic properties, including irreversible inhibition of platelet function, that distinguish it from the rest of the NSAID class. Further, data from long-term controlled clinical trials have clearly demonstrated that aspirin significantly reduces the risk of serious adverse CV events in certain patient populations (e.g., patients with a history of a MI). Aspirin, therefore, is an exception to the apparent "class effect" of increased risk for serious adverse CV events for NSAIDs described above. Data from large, long-term controlled clinical trials clearly showing no increased CV risk or a reduction in CV risk would be necessary before concluding that other NSAIDs are also exceptions to the class risk.

Recommendations

We summarize below our recommendations for appropriate regulatory actions for the NSAID class and select individual agents.

NSAIDs as a class

Boxed Warning and Contraindication

We recommend that the professional labeling (package insert) for all prescription NSAIDs, including both COX-2 selective and non-selective drugs, be revised to include a boxed warning highlighting the potential increased risk of CV events. The boxed warning should also include the well described risks of serious, and often life-threatening GI bleeding. We believe that a boxed warning with regard to potential

increased CV risk is an appropriate response to the currently available data and will serve to highlight to physicians and patients that they must carefully consider the risks and benefits of all NSAIDs, as well as other available options, before deciding on a treatment plan for relief of chronic pain and inflammation. If it is determined that chronic use of an NSAID is warranted for an individual patient, the boxed warning will help to emphasize the importance of using the lowest effective dose for the shortest duration possible along with appropriate attention to reduction of other risk factors for cardiovascular disease. The language of the boxed warning should be standardized across the class, with the exception of those situations where specific data or other information is available for an individual drug. In those cases, the standardized class wording should be maintained and the drug specific information added, including the results of any large controlled clinical trials.

The recommendation for a boxed warning for potential increased risk of CV events is supported by the unanimous vote of the Advisory Committees (28 yes) on the question of whether the labeling for the non-selective NSAIDs should be modified to include the absence of long-term controlled clinical trial data to assess the potential CV effects of these drugs.[9] While the AC did not specifically vote on a boxed warning, many of the committee members commented that such a warning would be an appropriate response given the current data. The Advisory Committees also strongly

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[9] There were 32 voting members of the Advisory Committees, but 4 members had left the meeting by the time this question was discussed.

supported boxed warnings for the individual COX-2 selective drugs for increased CV risk.

The recommendation that the boxed warning also include the well recognized serious, and often life-threatening, risk of GI bleeding associated with chronic use of NSAIDs is intended to further reinforce the existing bolded warning. The GI bleeding risk with NSAIDs is clearly consistent with our current approach to the use of boxed warnings, and placing this information in a boxed warning will serve to further emphasize this serious risk and ensure that physicians and patients keep this risk in mind as they are considering options for chronic therapy of pain and inflammation.

We also recommend that the labeling for all NSAIDs include a contraindication for use in patients in the immediate post-operative setting following CABG surgery. Data are only available in this setting from valdecoxib, but we have concluded that this short-term increased CV risk should be extrapolated to long-term use of valdecoxib. It is logical to also extrapolate this finding to other NSAIDs, pending the availability of other data that would suggest otherwise given the serious nature of the adverse events noted in the valdecoxib CABG study and the high-risk nature of the patients undergoing CABG surgery. The contraindication for NSAID use in this setting would NOT apply, however, to aspirin for the reasons noted above.

Medication Guide

We recommend that the patient labeling for all prescription NSAIDs, including both COX-2 selective and non-selective drugs, include a Medication Guide. The Medication Guide should focus on the potential

increased risk of serious adverse CV events and the risks of serious GI bleeding. The Medication Guide will also inform patients of the need to discuss with their doctor the risks and benefits of using NSAIDs and the importance of using the lowest effective dose for the shortest duration possible if treatment with an NSAID is warranted. To avoid confusion and to allow for more rapid implementation, we recommend that the text of the Medication Guide be standardized across the class, following the model that was recently successfully implemented for anti-depressants.

Comprehensive Data Review and New Studies

We recommend that the agency request that the sponsors of all non-selective NSAIDs conduct and submit for FDA review a comprehensive review and analysis of all available data from controlled clinical trials to further evaluate the potential risk of serious adverse CV events. The search and analysis strategy should be similar across sponsors and drugs. The agency should carefully review the data as they become available and take any appropriate regulatory actions based on the findings.

The agency should also work closely with sponsors of non-selective NSAIDs and other stakeholders (e.g., NIH, professional associations, patient groups) to encourage the conduct of additional long-term controlled clinical trials of the non-selective NSAIDs to better evaluate the potential for increased risk of serious adverse CV events.

Non-prescription NSAIDs

We recommend that the NSAIDs that are currently available without a prescription for the short-term treatment of acute pain continue to be available to

consumers. While this would apparently represent the first time that products that have a boxed warning in the prescription package insert would also be available for non-prescription use, we believe the available data support a conclusion that short-term use of low doses of the available non- prescription NSAIDs is not associated with an increased risk of serious adverse CV events. The overall benefit versus risk profile for the non-prescription NSAIDs remains very favorable when they are used according to the labeled instructions, and we believe that it is important to maintain a range of therapeutic options for the short-term relief of pain in the OTC market. Further, the other available non-prescription drugs for short-term relief of pain and fever can also be associated with serious, and potentially life-threatening, adverse events in certain settings and patient populations.

To further encourage the safe use of the non-prescription NSAIDs, we believe that the labeling for these products should be revised to include more specific information about the potential CV and GI risks, instructions about which patients should seek the advice of a physician before using these drugs, and stronger reminders about limiting the dose and duration of treatment in accordance with the package instructions unless otherwise advised by a physician. In addition, as noted earlier, the agency has determined that the labeling for non-prescription NSAIDs should be revised to warn of the potential for skin reactions. We also recommend that the Agency continue its current consumer education efforts regarding the safe and effective use of non-prescription pain relievers and that this new information be highlighted in those campaigns.

CELEBREX ®, NDA 20-998/NDA 21-156 (celecoxib capsules)

After carefully reviewing all the available data, we conclude that the benefits of celecoxib outweigh the potential risks in properly selected and informed patients. Therefore, we recommend that celecoxib remain available as a prescription drug with the revised labeling described below in addition to the NSAID class boxed warning, contraindication, and Medication Guide described above.

Boxed warning and other labeling changes

We recommend that the boxed warning for Celebrex include specific reference to the controlled clinical trial data that demonstrate an increased risk of serious adverse CV events (e.g., the APC trial). The text in the box may be brief and include a reference to the CLINICAL PHARMACOLOGY, Clinical Studies section of the labeling where the available long-term controlled clinical trial data should be described in greater detail. Finally, we recommend that the INDICATIONS section of the labeling be revised to clearly encourage physicians to carefully weigh the potential benefits and risks of celecoxib and other treatment options for the condition to be treated before a decision is made to use Celebrex, and to use the lowest effective dose for the shortest duration consistent with individual patient treatment goals.

Postmarketing study commitment

We strongly recommend that CDER request a written commitment from the sponsor to conduct an additional long-term study (or studies) to address the safety of celecoxib compared to naproxen and other appropriate active controls (e.g., other non-selective

NSAIDs, appropriate non-NSAID active comparators). CDER should be actively involved in the design of the trial(s) and insist on aggressive timelines for initiation and completion of the study(ies).

The above recommendations are consistent with the votes and recommendations made by the Advisory Committees for Celebrex. The Advisory Committees were unanimous in their conclusion that an increased risk of cardiovascular adverse events has been demonstrated for celecoxib. After carefully considering all the available data, the Advisory Committees voted 31 yes to 1 no in response to the question: "Does the overall risk versus benefit profile of celecoxib support marketing in the US?" While specific votes were not taken on the issue of what labeling changes and other risk management options would be appropriate, the overwhelming majority of the Advisory Committee member voiced their support for a boxed warning, a Medication Guide, and postmarketing study commitments to further explore the long-term safety of Celebrex in comparison to other appropriate comparators.

BEXTRA ®, NDA 21-341 (valdecoxib tablets)

After carefully considering all the available data and risk management options, we have concluded that the overall risk versus benefit profile for Bextra is unfavorable at this time. We therefore recommend that Bextra be withdrawn from the U.S. market. We have concluded, as noted above, that Bextra has been demonstrated to be associated with an increased risk of serious adverse CV events in short-term CABG trials and that it is reasonable from a public heath perspective to extrapolate these findings to chronic use. The increased risk of serious adverse CV events

alone, however, would not be sufficient to warrant withdrawal of Bextra since we have no data showing that Bextra is worse than other NSAIDs with regard to CV risk. Our recommendation for withdrawal is based on the fact that, in addition to this CV risk, valdecoxib already carries a boxed warning in the package insert for serious, and potentially life-threatening, skin reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme) and FDA has received 7 spontaneous reports of deaths from these reactions. The reporting rate for these serious skin reactions appears to be greater for Bextra than other COX-2 selective agents. Further, the risk of these serious skin reactions in individual patients is unpredictable, occurring in patients with and without a prior history of sulfa allergy, and after both short- and long-term use, which makes risk management efforts difficult. To date, there have been no studies that demonstrate an advantage of valdecoxib over other NSAIDs that might offset the concern about these serious skin risks, such as studies that show a GI safety benefit, better efficacy compared to other products, or efficacy in a setting of patients who are refractory to treatment with other products.

The recommendation that Bextra be withdrawn is supported, at least in part, by the specific votes and recommendations of the Advisory Committees. The Advisory Committees were unanimous in their conclusion that an increased risk of cardiovascular adverse events has been demonstrated for valdecoxib. In response to the question "Does the overall risk versus benefit profile of valdecoxib support marketing in the US?" the Advisory Committees voted 17 yes and 13 no with 2 abstentions. Several of the advisory committee members who voted no expressed concerns

about the strong signal of CV risk from the CABG trials, the absence of long-term controlled trial data to more clearly define the potential CV risks of Bextra, the fact that Bextra already carried a boxed warning for serious skin reactions, and the fact that there were no data to support a conclusion that Bextra offered a therapeutic advantage over NSAIDs.

One potential argument in favor of continued marketing of valdecoxib is that it provides an additional therapeutic option for management of arthritis and that prescribers and patients could be informed of the potential increased risk of CV events and serious GI bleeding, in addition to the potential for serious and possibly life-threatening skin reactions, and be allowed to make individualized treatment decisions. This approach, in fact, was strongly favored by practicing rheumatologists on the Advisory Committee. It is important to note, however, that there are more than 20 other NSAIDs on the market. This range of options diminishes the value of continued marketing of valdecoxib, particularly in the face of an already existing boxed warning regarding serious, and potentially life-threatening, skin reactions and the fact that there are no data that demonstrate that valdecoxib offers any therapeutic advantage over other NSAIDs.

We recommend that FDA request that Pfizer voluntarily withdraw Bextra from the U.S. market. If Pfizer does not agree to that request, we recommend that FDA initiate the formal withdrawal process by preparing and publishing a Notice of Opportunity for Hearing.

We recommend that FDA remain open to allowing limited access to valdecoxib under an IND to those

patients who believe that it is their best option, if the sponsor proposes such an IND. If additional clinical trials subsequently demonstrate that valdecoxib does not have an increased CV risk (or if its risk is significantly less than other available agents) or a therapeutic advantage for valdecoxib over other NSAIDs, FDA should carefully consider those data and reassess the current conclusions regarding the overall risks and benefits for valdecoxib.

VIOXX ®, NDA 21-042 (rofecoxib tablets and oral suspension)

VIOXX was voluntarily withdrawn from the U.S. market by the sponsor on September 30, 2004, following the announcement of the results from the APPROVe trial. Therefore, no regulatory action is warranted at this time. Should the sponsor seek to resume marketing for rofecoxib, a supplemental NDA with revised labeling will be required. The supplemental NDA would require FDA review and approval prior to implementation of the new labeling since the changes would not be of the type allowed under FDA regulations for a "Changes Being Effected (CBE)" labeling supplement The supplemental application should specifically outline the sponsor's proposal for revised labeling designed to provide for safe and effective use of the drug in populations where the potential benefits of the drug may outweigh potential risks, and all data and arguments that support resumption of marketing.

We believe that FDA should carefully review any such proposal submitted by the sponsor. We would also recommend that the FDA Drug Safety Oversight Board (DSB) and an advisory committee be consulted before a final decision is taken. Our rationale for

recommending review by the DSB and an advisory committee includes the following factors. First, there is limited precedent for a drug that has been withdrawn from the U.S. market for safety reasons to be returned to marketing. The only recent example that we can recall was Lotronex, and that application was reviewed by an advisory committee before FDA reached a final decision on the sponsor's request.[10] Second, concerns were expressed at the recent advisory committee meeting that Vioxx may be associated with a higher risk of increased blood pressure, fluid retention, and congestive heart failure than other COX-2 selective NSAIDs. We believe that these additional potential serious risks of Vioxx need to be fully explored through a public process before a decision is made regarding resumed marketing. Third, the recent advisory committee meeting was a general issues meeting, not one specifically devoted to the issue of resumption of marketing of Vioxx. While the committees narrowly voted in the affirmative that the overall risk versus benefit profile of rofecoxib supported marketing in the U.S., the committee members expressed a wide variety of often contradictory opinions on what regulatory actions (e.g., labeling changes, risk management efforts) would be appropriate to allow resumed marketing. Specific votes were not taken on these important issues, and we believe the agency would benefit from the advice of an advisory committee meeting specifically devoted to the resumption of marketing of Vioxx before the FDA reaches a decision on final action. Finally, the withdrawal of Vioxx has been the subject of intense public interest and debate,

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[10] The FDA Drug Safety Oversight Board had not been established at the time of the review of the Lotronex resubmission.

and we believe that a transparent process for reaching an agency decision on resumption of marketing is needed to ensure public confidence in the agency's decision-making process.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Mutual Pharmaceutical
Company, Inc.

Civil No. 08-cv-00358-JL

Videotaped Deposition of Robert Stern, a witness called by and behalf of the Plaintiff, taken pursuant to Federal Rules of Civil Procdure, before Nicole E. Guilbert, a Notary Public in and for the Commonwealt of Massachusetts, at Morrison Mahoney, 250 Summer Street, Boston, Massachusetts, on Monday, February 15, 2010, commencing at 8:53 a.m.

* * *

and I disagree with that being less than one in a hundred. But, again, your question is so long that I'm not sure exactly what he was responding to.

Q. Other than the question that's -- which he answers, would it be less than a one in a hundred chance, is there any other testimony on the first five pages of Exhibit 20 that you've now read that you disagree with?

A. So in his testimony as opposed to the other people who say, as I understand it, the strongest suspect or more likely than not, which I agree with, he seems to not use the same qualification of not this being the strongest suspect, which I do agree with, more likely than not the cause. He seems to have a level of certainty about it which I don't think one can go to at the level he seems to imply in response to your questions.

Q. Anything else you disagree with?

A. No, I don't think so.

Q. And I've asked you what you think about what they said. Let me just ask you what you think. Does Dr. Robert Stern agree that sulindac was the more likely than not cause of Karen Bartlett's SJS and TEN?

A. Yes.

* * *

Serious Adverse Reactions Associated With Sulindac
[excerpted article, references omitted]

Glen D Park, PharmD; Reynold Spector, MD; Thomas Headstream, MD; Mark Goldberg, MD

• Sulindac is a nonsteriodal anti-inflammatory agent that has been associated with serious adverse reactions. We saw four patients with reactions associated with sulindac. Our patients, one of whom died, had high temperatures and involvement of one or more organs, including the skin, liver, CNS, lymph nodes, bone marrow, and lungs. Eight similar previously reported cases also are summarized. In view of these cases of sulindac-induced toxicity, six of which were proved unequivocally by drug rechallenge, we suggest that physicians be cautious in prescribing this agent.

Sulindac was made available in the United States, in 1978, for use as a nonsteroidal anti-inflammatory agent. Early clinical studies indicated the occurrence of only relatively mild, adverse effects, including gastrointestinal tract and CNS toxic effects, rash, and transient elevations in liver function test results. However, during postmarketing clinical experience, reports began to accumulate describing serious adverse reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatotoxicity, pancreatitis, granulocytopenia, aplastic anemia, and thrombocytopenia.

We have seen four patients who had fever and involvement of one or more organs after therapy with sulindac. Two cases have already been reported and will only be reported briefly herein. The other two cases will be reported in detail.

REPORT OF CASES

CASE 1. -- A 40 year-old woman was referred to the University of Iowa Hospitals and Clinics (UIHC), Iowa City, from her community hospital, seven days after the onset of an acute febrile illness. The patient had a four-year history of facial lesions, clinically thought to be discoid lupus erythenatosus (LE), and a one-year history of arthralgias. Three weeks before her admission to the UIHC, therapy with sulindac, 150 mg twice daily, for the arthralgias was started. One week before admission, she had an illness, consisting of a sore throat, fever, and chills. She was treated empirically by her family physician with erythromycin. Three days before admission at UIHC, she was admitted to a community hospital after having diarrhea, nausea, vomiting, and a generalized maculopapular eruption with some blister formation. On examination, she was noted to be mildly icteric, with a total bilirubin level of 8.7 mg/dL (direct level, 6.3 mg/dL) and an SGOT level of 3.680 IU/L. Her WBC count was 3,300/cu mm. The sulindac therapy was discontinued. After three days, she was transferred to the UIHC, with worsening abdominal pain, an undiagnosed dermatologic condition, and no demonstrable infection.

On admission here, she was febrile (38.6 °C) and appeared acutely ill. Large areas of skin on her face, neck, chest, and upper part of her back had been denuded of epithelium. The lips were involved, but the oral mucosa appeared normal. Bullous lesions on the back and chest were flaccid and sloughed on palpation. Examination of her joints showed them to be normal, but the distal parts of her extremities were acrocyanotic. Her stool specimen was positive on

Hemoccult testing. The laboratory data were notable for the following: WBC count, 6,000/cu mm; platelet count, 146,000/cu mm; SGOT, 3,030 IU/L, SGPT, 789 IU/L; alka-line phosphatase, 275 IU/L, and bilirubin, 8.6 mg/dL (direct level, 7.7 mg/dL). The prothrombin time was 11 s (control time, 9 to 12 s) and the partial thromboplastin time was 46 s (control time, 32 to 39 s). An antinuclear antibody titer was 1:160, with a speckled pattern. The patient was treated with methicillin sodium, carbenicillin disodium, gentamicin sulfate, and methylprednisolone sodium sulfosuccinate intravenously. Soon after admission she required endotracheal intubation and mechanical ventilation for hypoxia and hypercapnia.

Twenty-six hours after admission, she died of progressive acidosis, hyperkalemia, and a coagulopathy. Postmortem exami-

Source, yr	Patient No./ Age, yr/Sex
Present Study	1/40/F
Present study and Dhand et, al 1981	2/29/F
Present study	3/57/M
Present study and Ballas and Donta, 1982	4/22/F
Anderson, 1979	5/18/F
Wolfe, 1979	6/46/M
Fein, 1981	7/39/F
Russell, 1980	8/26/F
Smith and Lindberg, 1980	9/18/M
Levitt and Pearson, 1980	10/75/M
Lily, 1981	11/52/M
Kaul et al. 1981	12/12/F

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[1294]

was discharged from the hospital on a tapering prednisone regimen two weeks after admission.

CASE 4. -- A 22 year old woman was admitted to the UIHC two months after her condition was diagnosed as systemic LE. She had been treated for polyarthralgias with sulindac for three months before this diagnosis was made. At that time, the sulindac therapy was discontinued and treatment with prednisone, 20 to 40 mg/day, was begun for the two months before admission. During the last two weeks before admission, her local physician began tapering the prednisone doses. On the day of admission, the sulindac therapy was restarted. About one hour after the first dose (150 mg) she had generalized proritus followed by shortness of breath, pleuritic chest pain, visual blurring, photophobia, occipital headache, cramping abdominal pain, and a fever of 1.6 °C. She did not have a rash, wheezing, arthralgias, myalgias, or focal neurologic signs. She was given an oral dose of prednisone (60 mg) and was transferred to the UIHC. At the time of hospital admission, she was mildly lethargic, had questionable nuchal rigidity, and a temperature of 38 °C. Her WBC count was 28,900/cu mm with a left shift, an ESR was 18 mm/hr (Westergren), and liver function test values were normal. Her CSF appeared hazy and contained 2,210 WBCs per cubic millimeter, with 95 neutrophils, 13 RBCs per cubic millimeter, a glucose level of 42 mg/dL (serum glucose level, 125 mg/dL), and a protein level of 522 mg/dL. Gram's stain and bacterial and fungal cultures were negative as were cryptococcal antigen and viral titers. Initially, she was treated with

penicillin G potassium and chloramphenicol sodium succinate. During a four-day period, her fever defervesced, and findings from a repeated lumbar puncture showed a clear CFS with 13 WBCs per cubic millimeter, with 25% neutrophils and a protein level of 73 mg/dL. She was discharged from the hospital after completing a ten-day course of penicillin and was feeling well. Three weeks after the initial lumbar puncture, a repeated examination of her CSF showed no abnormalities.

COMMENT

We conclude from these four cases that sulindac is the probable cause of a serious adverse reaction, manifested by fever and involvement of one or more organs. Case 2 is the strongest case by virtue of the recurrence of clinical and biochemical evidence of hepatotoxicity on rechallenge with the drug. Cases 1 and 3 can be classified as probable adverse reactions to sulindac. Although the toxicity of griseofulvin must be considered a possibility in case 3, toxic reactions of this type have not been verified with griseofulvin. We consider it unlikely that griseofulvin was the causative agent. Case 4 is the weakest case; we can only say there was a "possible" relationship between the sulindac administration and the aseptic meningitis. However, the timing is appropriate, and there is a distinct similarity in manifestation with ibuprofen-induced aseptic meningitis.

Our four cases of sulindac-induced reactions characterized by fever and involvement of one or more organs have much in common with each other and eight other cases reported in the literature. The Table gives the organ involvement, time on onset, and outcome in our four cases and the eight cases from the

literature. In these 12 cases, fever, skin involvement, and hepatotoxicity were prominent (Table). Other organs or systems involved in this reaction are the CNS (two cases), lymph nodes (two cases), lungs (three cases), bone marrow (one case), pancreas (one case), and blood vessels (hypotension, one case). Other cases have been verified with sulindac-induced involvement of one organ (eg, pancreatitis), proved by rechallenge, but without the presence of fever.

The mechanism by which sulindac produces these reactions is unclear. The clinical data do not prove an immunologic mechanism, although circulating immune complexes, total complement and C3 and C4 levels were not done in all patients and more specific immunologic studies were not done. Skin biopsy specimens in cases 1 (after death) and 3 were nonspecific, with regard to cause. Similar reactions have been reported with ibuprofen, preponderantly in patients with systemic LE. The basis of the relationship of these reactions to systemic LE is not clear. Patients with systemic LE are more likely to have multiple drug allergies. Although a diagnosis of systemic LE is well represented in the Table, there are no obvious differences in the syndrome between those patients and patients without an apparent immunologic disease process. Finally, it seems unlikely that a pharmacologic effect, ie, inhibition of prostaglandin synthetase, plays an important role, since other nonsteroidal anti-inflammatory agents have been used before and after the reaction in some patients without eliciting a similar response.

On the basis of similarities in the 12 cases reviewed in the Table and the fact that six of the cases were proved by rechallenge, we believe this syndrome is a

potentially fatal complication of sulindac therapy. Clinicians should use caution in prescribing sulindac therapy, reserving its use for patients not responding to adequate doses of aspirin or other less toxic anti-inflammatory agents and avoiding the use of this agent solely as an analgesic.

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An Expanded Profile of Cutaneous Reactions to Nonsteroidal Anti-inflammatory Drugs

Reports to a Speciality-based System for Spontaneous Reporting of Adverse Reactions to Drug

[excerpted article, references omitted]

Robert S. Stern, MD, Michael Bigby, MD

• The nonsteroidal anti-inflammatory drugs are widely used in the United States and are a frequent cause of cutaneous reactions. since December 1980, dermatologists have reported 135 of these drug reactions to a specialty-based Adverse Drug Reaction Reporting System. Reactions to piroxicam were most frequently reported; the majority of reactions to this drug were vesiculobullous and occurred most often in sun-exposed areas. Other reactions to nonsteroidal anti-inflammatory drugs not previously recognized include serum sickness, exfoliative erythroderma, and photosensitivity associated with sulidac; toxic epidermal necrolysis was reported with tolmetin, zomepirac sodium, and piroxicam. Fixed drug eruptions were noted with ibuprofen and naproxen, and photosensitivity was reported with sulindac and indomethacin. These findings illustrate the usefulness of a specialty-based system for spontaneous reporting of new and serious adverse reactions to drugs. (*Jama* 1984; 252: 1433-1437)

IN THE past decade, many new non-steroidal anti-inflammatory drugs (NSAIDs) have been introduced into the United States and are now widely used to treat a variety of conditions, including inflammatory and degenerative musculoskeletal disorders. Several

comprehensive reviews discuss the indications, mechanisms of action, pharmacology, efficacy, and toxicity of these drugs. However, these reviews are limited in their attention to cutaneous reactions to NSAIDs. Bailin and Matkaluk have reviewed the cutaneous reactions to rheumatological drugs, but have discussed only two of the NSAIDs introduced since 1965.

Since its inception in December 1980 through July 1983, the Adverse Drug Reaction Reporting system (ADRRS), a system administered by the American Academy of Dermatology for the spontaneous reporting of suspected adverse reactions to drugs, has received 135 reports of adverse cutaneous reactions to NSAIDs. This study presents reactions to NSAIDs reported to the ADRRS, with emphasis on newly reported cutaneous reactions.

METHODS

The ADRRS of the American Academy of Dermatology was organized in late 1980 to facilitate the reporting of new, unusual, or serious suspected adverse drug reactions. To simplify and encourage reporting, a toll-free telephone number (1-800-323-1473) is available 24 hours each day, seven days a week. During business hours, this telephone is answered by a trained project assistant in the American Academy of Dermatology's office. During other hours, a voice-activated answering machine is available. Reporters and patients are assured of confidentiality, and each reporter is furnished with a transcript of their report for verification. Telephone reports account for more than 90% of reports received from December 1980 through July 1983. Written reports account for the remainder.

All reports are reviewed for completeness by a board-certified dermatologist. If needed, supplementary information may also be requested from the reporter. Completed reports are classified according to established algorithms for judging the type, severity, and outcome of reactions based on a standard vocabulary.

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[2482]

Table 2.—Ratio of Reactions Reported to the ADRRS* to Relative Number of New Prescriptions Dispensed

Drug	Relative No. of New Prescriptions Dispensed†	No. of Persons With Reactions Reported to ADRRS	Ratio of Reactions Reported to Relative Prescriptions Dispensed
Benoxaprofen	1.0	15	.15
Piroxicam	5.7	49	8.6
Meclotenamate sodium	2.7	15	5.6
Sulindac	8.4	18	2.1
Zomepirac Sodium	10.7	19	2.1
Tolmetin	3.4	3	0.9
Naproxen	14.2	6	0.4
Fenoprofen	5.0	2	0.4
Ibruprofen	26.9	7	0.3
Indomethacin	12.7	1	0.1

* ADRRS indicates Adverse Drug Reaction Reporting System.
† Market and prescription data © copyright 1981-1983, IMS America Ltd. Benoxaprofen had the smallest number of prescriptions dispensed from July 1981 to June 1983. The number

of prescriptions for all other drugs are expressed as a multiple of the number of benoxaprofen prescriptions for this period.

Table 3.--Cutaneous Reactions to NSAIDs Reported to the ADRRS*

Drug	Newly Reported†	Previously Reported and Requiring Hospitalization or Bed Rest†
Sulindac	Exfoliative erythroderma, photosensitivity, serum sickness‡	Toxic epidermal necrolysis (2)
Tolmetin	Toxic epidermal necrolysis‡	...
Zomepirac sodium	Toxic epidermal necrolysis‡	Urticaria, exanthema, anaphylaxis
Ibuprofen	Vesiculobullous, ‡ fixed drug	Vasculitis, erythema multiforma
Naproxen	Erythema multiforme, vesiculobullous (2), fixed drug	Serum sickness
Benoxaprofen	Alopecia	...
Piroxicam	Erythema multiforme (2), vesiculobullous (29), ‡ photosensitivity (36)	Urticaria, maculopapular rash, rash (unspecified)
Indomethacin	Photosensitivity	...
Meclofenamate sodium	...	Erythema multiforme, vasculitis, vesiculobullous

* NSAIDs indicates nonsteroidal anti-inflammatory drugs; ADRRS, Adverse Drug Reaction Reporting System. Reactions included were not previously noted in the English literature or requiring hospitalization or bed rest.

† The number of cases reported appears in parenthesis if more than one case was reported.
‡Indicates at least one patient with reaction of this type who required hospitalization or bed rest.

Reports are also classified by the degree of causality between each drug and its adverse occurrence with this drug; it was suspected in only one of 15 reported reactions. Vasculitic, purpuric, or petechial eruptions were noted in four cases, a rate significantly higher than that reported for other NSAIDs ($P<.05$, Fisher's exact test). Three serious reactions (erythema multiforme, vasculitis, and a vesiculobullous eruption) occurred in association with meclofenamate sodium exposure.

The majority of cutaneous reactions to zomepirac sodium were anaphylactoid in nature. Reactions to this drug that were reported to our system included four cases of anaphylaxis, two cases of angioedema, and seven cases of urticaria. Other new and serious reactions included a case of toxic epidermal necrolysis, which had not been previously reported with this drug. Zomepirac acid was withdrawn from the US market in March 1983.

Sulindac was associated with a wide variety of adverse cutaneous reactions (Table 1). One eruption in a sun-exposed distribution suggested photosensitivity. This eruption, along with two other serious reactions, a case of a serum sickness-like syndrome and one of exfoliative erythroderma, had not been noted previously. The case of serum sickness, as well as two cases of toxic epidermal necrolysis, required bed rest or hospitalization.

Of the remaining five NSAIDs with new prescription rates at least as great as that of

benoxaprofen during this period, only two had more than five reported reactions: naproxen and ibuprofen. Since both of these drugs had relatively high prescription rates, there were relatively small ratios of reactions to new prescriptions (Table 2). Three previously unreported types of reactions (erythema multiforme, a vesiculobullous eruption, and a fixed drug eruption) were reported in association with naproxen. The latter two types of reactions were also newly reported to us with ibuprofen. Tolmetin, a NSAID structurally similar to zomepirac acid, was associated with toxic epidermal necrolysis, a reaction not previously reported with this drug. A case of indomethacin-related photosensitivity, which was established by rechallenge and photopatch testing, was also reported. Reactions reported to the ADRRS not previously reported in our review of the English literature, as well as those requiring hospitalization or bed rest, are summarized in Table 3. (A supplemental bibliography consisting of the 111 manuscripts we reviewed is available through NAPS.)

Two deaths occurred among those patients with adverse cutaneous reactions to NSAIDs reported to the ADRRS. Toxic epidermal necrolysis developed in an 81-year old woman with in 12 to 14 hours of taking zomepirac sodium for an unknown indication. She had no known previous exposure to zomepirac sodium. The patient died of complications of toxic epidermal necrolysis after a 14-day hospitalization. Toxic epidermal necrolysis developed in an 82-year-old woman 14 days after starting on a regimen of sulindac. She had no known history of previous exposure to sulindac and had not recently begun taking any other drugs. She died of complications of toxic epidermal necrolysis in eight days.

COMMENT

Nonsteroidal anti-inflammatory drugs, a chemically heterogeneous group of compounds, can cause a wide variety of cutaneous reactions. As a result of the cooperation of the dermatologists who shared their observations with the ADRRS, we have been able to expand our knowledge of the spectrum of cutaneous reactions associated with NSAIDs.

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Allergic Cutaneous Reactions to Drugs [excerpted article, references omitted]

Michael Bigby, MD,* Robert S. Stern, MD and
Kenneth A. Arndt, MD

Our goal in this article is to review adverse cutaneous reactions to drugs that are known or presumed to be allergenic. Attributing a drug eruption to drug allergy implies that an antigen-specific, antibody, and/or T-cell-mediated immune response can be demonstrated. While the pathophysiology of some types of drug eruptions is well understood, we are severaly limited in our understanding of the pathophysiology of most presumably allergic cutaneous reactions to drugs. Some cases of drug-induced urticaria, for example, are due to IgE-mediated, immediate-type hypersensitivity. Allergic contact dermatitis to topical medications is an example of helper-T-cell--mediated delayed-type hypersensitivity. In contrast, the pathophysiology of drug-induced exanthems, toxic epidermal necrolysis, erythema multiforme, and many other drug eruptions is poorly understood.

The presumption that a drug eruption is due to allergy is often based on clinical features. There are several clinical features of a drug-associated rash which suggest that it is due to immune mechanisms: the reaction should occur in only a small percentage of patients exposed to the drug; the reaction should not be dose dependent; the onset of the rash should occur in only within the first one or two weeks after drug therapy is instituted; the rash is accompanied by other signs and symptoms suggestive of drug allergy, for example, fever, pruritus, or eosinophilia; and finally, the rash should resolve when the suspected drug is

discontinued and should reappear *if* the patient is rechallenged with the responsible drug.

Determining that an eruption is caused by a particular drug is often difficult, especially when the patient is taking multiple drugs and/or has intercurrent illnesses. There are established algorithms that are useful for classifying the degree of casuality between drugs and observed adverse cutaneous reaction. The algorithms are widely used in the literature and are useful in clinical practice.

* * *

[719]

[T]opical preparations containing neomycin can easily be avoided. Ethylenediamine is a stabilizer found in many topical preparations. It cross-reacts with aminophylline and several of the antihistamines (for example, tripelennamine and hydroxyzine). Patients who were sensitized to ethylenediamine topically may develop "systemic allergic contact dermatitis" if exposed to aminophylline or cross-reacting ntihistamines *systematically*. Systematic contact dermatitis, is manifested by the development of a generalized eczematous dermatitis is manifested by the development of a generalized eczematous dermatitis dyshidrotic eczema of the hands, or a localized dermatitis at the site of previous contact with the sensitizing medication. Systemic contact dermatitis is quite rare.

Contact dermatitis also occurs in sites where transdermal patches are applied. Allergic contact dermatitis develops in approximately 15 to 20 per cent of patients using transdermal clonidine. The prevalence of allergic contact dermatitis among users

of transdermal nitroglycerine and scopolamine is lower. Irritant contact dermatitis is common in patients undergoing long-term therapy with any transdermal medication.

Identifying the responsible topical, inciting agent is essential for successful therapy of contact dermatitis. In confusing cases patch testing may provide invaluable information. In the acute stages of allergic contact dermatitis is treated with warm compresses (for example, aluminum acetate, normal saline, or water) and a topical corticosteroid lotion or cream. In the more chronic stages especially if lichenification is present, hydration and the use of a topical corticosteroid ointment is indicated. It is important to inform the patient that three weeks or more is often required for the rash to resolve completely. In severe cases when both eyes are swollen shut or when large areas are involved a short course of prednisone (approximately 1 mg per kg daily for seven days followed by a rapid taper over the next seven to ten days) can significantly shorten the normal duration and lessesn the severity of the disease.

Toxic Epidermal Necrolysis, Erythema Multiforme, and fixed Drug Eruptions.

These three entities are considered together because of the marked similarity of their pathologic features. It has been widely suggested that their pathogenesis may also be similar.

Toxic epidermal necrolysis is a catastrophic illness with significant morbidity and a high rate of mortality. It has an acute onset and is often heralded by a brief prodrome of a sore throat, high fever, chills, and malaise. With 24 hours, the skin becomes tender and small dusky, necrotic macules begin to appear. Early

and extensive involvement of periorificial areas and mucous membranes is characteristic. Necrotic areas enlarge rapidly and become confluent. During the peak of the disease, large sheets of full-thickness epidermis separate from the underlying dermis in response to minimal trauma (Fig. 1). Conjunctival injection is invariably present. Within two to five days, extensive areas of epidermis slough, leaving large denuded areas. The patient is acutely ill and mortality rates between 15 and 60 per cent have been reported.

Patholotically, there is full-thickness epidermal degeneration and necrosis. The epidermis separates from the underlying dermis along the dermoepidermal junction. An extremely sparse lymphocytic infiltrate may be present. The pathophysiology of toxic epidermal necrolysis is unknown.

Drugs are most often implicated as the cause of toxic epidermal necrolysis. Two large series of cases have been reported. The drugs most commonly implicated are the NSAIDs (especially phenylbutazone, oxyphenbutazone, sulindac, and piroxicam), antibiotics (especially trimethoprim-sulfamethoxazole), the barbiturates, phenytoin, and allopurinol. In the most recent report, the

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[720] [IMAGE OMITTED]

NSAIDs accounted for 33 per cent of 87 cases studied. Accurate incidence figures are, however, not readily available. Fortunately, toxic epidermal necrolysis is uncommon.

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Drug-Induced Toxic Epidermal Necrolysis

[excerpted article, references omitted]

Pierre E. Wolkenstein, MD
Jean C Roujeau, MD
Jean Revuz, MD

In his 1956 article, Lyell described four patients with a "scalded skin" appearance due to drug therapy, staphylococcus, and idiopathic causes. In fact, his original article included three completely different diseases: generalized fixed drug eruption, staphylococcal scalded skin syndrome (SSSS), and toxic epidermal necrolysis (TEN), which now constitute three well-separated entities. With further case reports and some large series our knowledge of TEN has improved. TEN is now currently defined by extensive detachment of full-thickness epidermis most often related to adverse drug reaction.

Our understanding of TEN has undergone several changes in the past years. We will review nosology, clinical features, epidemiology, drug causes, pathogenesis, and treatment of TEN.

Nosology of Toxic Epidermal Necrolysis

In 1922 Stevens and Johnson described two febrile children with erosive stomatitis, severe conjunctivitis, and a disseminated cutaneous eruption. This eruption consisted of discrete dark, red macules sometimes with a necrotic center. For these authors, this new disease was distinct from erythema multiforme. Lyell in his first description of TEN made no reference to Stevens-Johnson syndrome. Indeed, the patients of Stevens and Johnson had no blisters and no extensive detachment of the epidermis; however, it soon became evident that severe forms of Stevens-Johnson syndrome could lead to TEN and that both diseases

could be induced by the same drugs. In light of these observations many people considered Stevens-Johnson syndrome as the minimal form of TEN spectrum.

Conversely, targetlike lesions are present in most of TEN cases around the areas of epidermal sloughing and, by analogy, many observers included Stevens-Johnson syndrome and TEN into the erythema multiforme spectrum. Therefore, the nosology for severe acute bullous disorders related to drugs or infections remains controversial. Severe cases of erythema multi-forme are sometimes referred to as erythema multi-forme (EM) major or as Stevens-Johnson syndrome. One case diagnosed as Stevens-Johnson syndrome (SJS) by one physician might have been called TEN by another.

Most of the confusion on the classification resulted from the assimilation of EM major to SJS because of the prominent mucous membrane erosions in both situations; nevertheless, it is possible to separate EM major from SJS on the basis of clinical symptoms, pathologic findings, and causes. Thus, EM major is defined by mucosal erosions with characteristic skin lesions, typical targets with or without blisters with a symmetrical and mainly acral distribution. SJS presents with mucosal erosions, with widespread purpuric cutaneous macules, mainly of truncal distribution, sometimes confluent with positive Nikolsky's sign and epidermal detachment. There is a clear correlation between clinical pattern and etiology: EM is usually recurrent, post-infectious, with low morbidity and no mortality. Conversely, SJS is a severe drug-induced disease with high morbidity, and its prognosis may be poor in some patients.

The EM spectrum, including EM major and EM minor, is separated from a TEN/SJS spectrum. Both SJS and TEN are severity variants of the same drug-induced process. This concept of a continuous spectrum from SJS to TEN fits with a previously proposed classification and denomination of "acute disseminated epidermal necrosis" (ADEN), type 1 corresponding to SJS, type 3 to TEN, and type 2 to transitional cases. Because the extent of necrolysis is one of the principal prognosis factors, the limit of 10% of the body surface area involved by epidermal detachment was used as an arbitrary boundary between SJS and TEN. Recently, a consensus agreement was made on a 3-grade classification within the SJS/TEN spectrum. SJS includes cases with mucosal erosions plus widespread purpuric macules and epidermal detachment below 10%; transitional SJS-TEN, cases with widespread purpuric macules, and epidermal detachment between 10% and 30%; and TEN, cases with widespread purpuric macules and epidermal detachment above 30%.

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[401]

Epidemiology of Toxic Epidermal Necrolysis

Cases of SJS and TEN remain very rare. Only few studies appreciated the incidence of TEN in the population. The first study came from Sweden: In the Uppsala region, three cases occurred in a population of 1.2 million in the period 1964 through 1969, giving a rate of new TEN cases of 0.4 per million inhabitants per year. The study of Chan et al., based on discharge diagnoses at Group Health Cooperative of Puget Sound (Seattle, Washington) from 1972 through 1986, gave an incidence of TEN of 0.5 per million of inhabitants per

year. Two epidemiological studies of TEN in France and Germany from 1981 to 1985 gave the following results: In France, 333 cases occurred during this period in a population of 54.7 million giving a rate of 1.2 cases per million population annually. In West Germany, the incidence was about the same, 1 case per million per year, with 259 new cases of TEN during period in a [402] population of 64 million. It is not clear whether this difference (0.4 to 1.5 cases per million per capita per year) reflects a rising occurrence in recent years, a different case definition, or sampling variations. A recent epidemiological study cited an incidence of 1.89 cases per million population per year for SJS and TEN in Germany from 1990 to 1992. There are regional disparities in drug prescriptions as well as in the genetic background, which has been shown to increase the risk of TEN. Nevertheless, TEN appears to be a rare disease.

Toxic epidermal necrolysis has been observed worldwide and has been described in all human populations. Geographic origins of papers about TEN give evidence of the cosmopolitan distribution of this disease: Africa, America, Asia, and Europe. Nevertheless, no epidemiological data are available on ethnic variations in incidence of TEN. It is noteworthy that this disease is not limited to human beings. Although uncommon in the veterinary population, a few cases have been reported in dogs, cats, and in a research monkey after drug therapy.

In the two epidemiological studies from France and Germany between 1981 through 1985, the male/female ratio was 0.6. This predominance of women was confirmed by other data, with a male/female ratio from 0.5 to 0.7 in TEN. In fact, a similar excess of females

has been observed for most adverse drug reactions. One possible explanation is more frequent drug intake by women, but the incidence of cutaneous drug reaction is reportedly 35% higher in women than in men when normalized for the number of drugs received, age, diagnosis, and survival. In children, TEN has a balanced sex ratio.

In our department, a comparison was performed between the series of 87 cases of TEN from 1972 to 1985, and the series of 90 cases from 1985 to 1991. In the last series the sex ratio was 1, instead of 0.6 male/female ratio in the previous series. This change in sex ratio observed in the last years resulted from the increased number of human immunodeficiency virus (HIV)-infected patients suffering from TEN. In the recent series 20 patients among 90 with TEN cases were HIV-infected, and 16 were men. Thus, the high prevalence of HIV infection contributed to equalizing the sex ratio. Among non-HIV-infected persons with TEN, the male/female ratio was the same as in our previous series (0.62 vs. 0.58).

Toxic epidermal necrolysis occurs in all age groups, including children, infants, and even newborns. In the French epidemiological study from 1981 to 1985, the mean age of patients was 46.8 years, with extremes of 1 and 93 years; 13.8% of cases were observed in children below 16 years of age. In the German epidemiological study on the same period, the mean age for patients presenting with TEN was 63 years. The incidence of TEN increases sharply with age. This increase is correlated to the more frequent drug intake in the elderly. Thus, in one study involving hospital inpatients, the risk of a mild drug reaction was increased twofold in patients over 60 years of age.

With HIV-infected patients among TEN patients, we observed a younger mean age. In the Creteil series of drug-induced TEN in patients infected with HIV between 1984 and 1989, the mean age was 35.4 +/- 7.2 years.

When comparing our series of 90 cases from 1985 to 1991 to our series of 87 cases of TEN from 1972 to 1985, the prevalence of HIV infection was 22%, and only 1%, respectively. In a previous series of 14 HIV-infected patients with TEN, all but one were men, with a mean age of 35.4 +/- 7.2 years. All exhibited a low CD4 cell count. Although this study had no epidemiological implication, informal approaches strongly suggested that the risk of developing TEN was considerably increased in HIV-infected patients. During the study period 17.5% of TEN patients were HIV-infected patients, whereas the prevalence of HIV infection was less than 0.4% in the general population. During the same period, 15 cases of TEN occurred in a population of 5102 patients with AIDS, whereas 0.04 were expected according to the incidence of the disease in the general population. Two explanations have been proposed for this finding: (1) the greatly increased number of drugs used in AIDS patients compared with other patients, and (2) the HIV infection itself with its virus-induced immunodeficiency and associated infections. The rate of cutaneous adverse reaction to trimethoprim-sulfamethoxazole in the general population is approximately 3%. This incidence increases to 29% to 70% in patients with AIDS.

The incidence of TEN among patients with bone marrow transplantation has not been evaluated, but TEN appears not to be as infrequent as previously thought in bone marrow recipients. In the Creteil

center, nine cases of TEN were studied retrospectively on 152 patients having received allogeneic bone marrow transplantation from 1978 to 1985. In this homogeneous series, the incidence observed was 6%. This incidence is too high to be a coincidence. In some cases (5 of 9), TEN appeared to be clearly related to acute graft-versus-host disease. In other cases (4 of 9), TEN was more likely drug-induced. Thus, TEN in bone marrow recipients seems to be related to a drug reaction (to sulfonamides or to other antibiotics) as often as to graft-versus-host disease.

Several cases of TEN have been reported in patients with systemic lupus erythematosus. The simultaneous occurrence of these two diseases is rare, but yet too frequent to be a simple coincidence.

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[403]

Drug Causes of Toxic Epidermal Necrolysis and Factors Other Than Drugs

It became generally accepted that TEN was a drug reaction after the distinction was made between SSSS and TEN. In a consensus workshop in the 1980s it was agreed that "reaction to drugs was to date the only documented cause of TEN" with the exception of graft-versus-host disease. This conclusion recognized the existence of "idiopathic cases." Nevertheless, it is worth to note that in the two epidemiological studies from France and Germany between 1981 through 1985, only a small number of patients (4.5% and 3%, respectively) with TEN had not taken any drugs. In the French study, 10 patients with TEN denied any drug intake or chemical exposure. Among them, one had a severe infection with herpes simplex virus, and

two had *Mycoplasma pneumoniae* pulmonary infection. These cases constitute exceptional infection-induced TEN. Thus, the vast majority of TEN cases are related to chemicals systemically administered as drug therapy. In the French retrospective epidemiological study, for each patient, a mean of 3.6 drugs were found to have been administered systemically within the 3 weeks before the beginning of the TEN. The culprit drugs implicated in most series were antibacterial sulfonamides, anticonvulsants, allopurinol, pyrazolone derivatives, and, less frequently, other nonsteroidal anti-inflammatory drugs.

Sulfonamides

In 1942, before the publication of Lyell's article, researchers described a pemphigus-like eruption associated with sulfadiazine, which was probably the first sulfonamide-induced case of TEN. Antibacterial sulfonamides constitute the most frequently drugs implicated in TEN. Thus, about 30% of drug-induced cases of TEN in published series are related to sulfonamides. The long-acting sulfonamides carry a high risk of TEN. This high risk has been emphasized by two campaigns of mass prophylaxis with long-acting sulfonamides. During the first one in Morocco in 1967, sulformethoxine was distributed to 110,000 persons for the prevention of meningococcal meningitis. Several dozen cases of Stevens-Johnson syndrome and TEN were observed. Among these cases, 11 resulted in death.

During the second campaign in Mozambique in 1981, sulfadoxine was distributed to 149,000 persons for the prevention of cholera. A total of 22 cases of Stevens-Johnson syndrome were observed, with three deaths. Because trimethoprim-sulfamethoxazole

association is the most used sulfonamide, it is now one of the most frequently associated with cases of TEN, even though the risk is probably lower than with long-acting sulfonamides. This risk has been estimated to be 0.2 cases of TEN per million daily doses. The proportion of sulfonamides in the published series was high in the 1960s and 1970s. Up to 1985, this relative proportion of sulfonamides decreased with the years. But when we compared our series of 90 cases of TEN from 1985 to 1991 to our series of 87 cases of TEN from 1972 to 1985, there was a shift in the distribution of culprit drugs, with an increase in cases related to antibacterial sulfonamides.

In our recent series, 20 patients among 90 were infected by HIV Among these 20 HIV-infected individuals, TEN was attributed to 23 drugs. These drugs were mainly sulfonamides (sulfadiazine in 11 cases, sulfadoxine-pyrimethamine in 3 cases, and sulfamethoxazole-trimethoprim in 4 cases). It is clear that the increased number of TEN cases attributed to sulfonamides results from the treatments of opportunistic infections of AIDS. This is mainly true for sulfadiazine and sulfadoxine. All 11 cases attributed to sulfadiazine and 3 of 4 attributed to sulfadoxine occurred in AIDS patients treated for cerebral toxoplasmosis. Four of 13 cases complicating the administration of sulfamethoxazole and trimethoprim were observed in HIV-infected individuals.

Anticonvulsants

In 1942 researchers reported three cases of a bullous eruption with mucous membrane involvement attributed to barbiturates, and phenytoin. Later, phenytoin, barbiturates, and carbamazepine have been

reported to induce TEN. Phenytoin carries probably the highest risk. In children, anticonvulsants are the main inducers of TEN. In adult patients who are receiving anticonvulsants, TEN is often associated with concurrent radio-therapy or chemotherapy for malignant cerebral tumours. Owing to a common metabolic pathway, phenobarbital, phenytoin, and carbamazepine may include cross reaction, and all three drugs should be contraindicated following TEN because of one of these agents.

NSAIDS

Every drug in all nonsteroidal anti-inflammatory drug (NSAID) classes has been involved in at least a few cases, but they appear to have different risks. NSAIDs with long half-lives (pyrazolones, oxicams, fenbufen, sulindac) are suspected to have higher risks. Pyrazolone derivatives have been cited in most series as important inducers of TEN. In France, the risk linked to isoxicam was about 10 times higher than the risk linked to piroxicam, despite identical indications, closely related chemical structures, and comparable half-lives. Two of the NSAIDs with highest risks of TEN in the epidemiological French study from 1981 to 1985, isoxicam and oxyphenbutazone have been withdrawn from the French pharmacopeia. The withdrawal of these two drugs may explain the lower number (19 cases) of TEN attributed to NSAIDs in our recent series of 90 consecutive TEN. In our previous series, 29 cases of TEN among 87 were attributed to NSAIDs. Among these 29 cases [404], 16 were attributed oxyphenbutazone and 5 to isoxicam.

* * *

A 10-Year Experience With Toxic Epidermal Necrolysis

[excerpted article, references omitted]

J T. Schulz, MD, PhD, R.L. Sheridan MD, C.M. Ryan MD, B. MacKool, MD, and R.G. Tompkins MD, ScD.

Toxic epidermal necrolysis is a devastating medication-induced desquamation disorder with a reported mortality rate of 30% to 60% in adults. Data from preciously reported series suggest that age, delay in referral to a burn center, total body surface area (TBSA) involvement, and systemic steroid treatment are poor prognostic indicators. We reviewed the records of 39 patients treated in out burn center over the past 10 years and found that the mortality rate was significantly correlated with age, thrombocytopenia, and delay in presentation. Steroid treatment and TBSA involvement were not significantly related to the mortality rate. Thirty-nine adult patients with grater than 20% TBSA epithelial necrosis were cared for in our center from January 1987 to March 1998. Wounds were treated with topical antimicrobial medications and porcine xenografts in a bacteria-controlled nursing unit. We reviewed the records of these patients for 28 clinical characteristics and looked for clinical correlates of mortality by single analysis of variance. The mortality rate was 44% (17 of 39 patients); the cause of death was most commonly multiple-organ dysfunction syndrome, for which a microbial etiologic agent was not always identified. Autopsies were performed on 11 of the 17 patients who died; there was evidence of multiple-organ damage. The patients who survived and the patients who died did not differ significantly in TBSA epithelial necrosis (66% ± 6% vs 72% ± 5%, respectively), admission

platelets, number of nosocomial infections, number of complications, preadmission exposure to steroids, or extent of mucosal involvement. When compared with the patients who died, the patients who survived were (1) 20 years younger (47.5 ± 4.2 years vs. 64.5 ± 5.3 years). (2) admitted to the hospital sooner after the onset of their rash (3.5 ± 0.4 days vs 5.9 ± 1.0 days), (3) much less likely to experience early thrombocytopenia (platelet nadir, 154 ± 24 vs 70 ± 18), (4) more likely to be febrile on presentation, and (5) less likely to have been treated with antibiotics before referral to our unit. These differences were statistically significant. The most common etiologic agents were antibiotics, anticonvulsants, and nonsteroidal anti-inflammatory drugs. Our results for a group of older patients with toxic epidermal necrolysis with extensive skin involvement suggest that age, delay in hospitalization, thrombocytopenia, and early empiric antibiotic treatment are associated with a poor prognosis. (J Burn Care Rehabil 2000; 21:199-204)

Among the most feared complications of medication exposure are the exfoliative skin disorders - erythema multiforme major, Stevens-Johnson syndrome, and toxic epidermal necrolysis (TEN). These syndromes share the histopathologic feature of disruption of the epidermal-dermal junction which results in subsequent epithelial loss and vulnerability to bacterial and fungal infections. Epithelial loss may also occur in the oropharynx, the gastrointestinal tract, the tracheobronchial system, and the external eye, which predisposes the patient to nutritional, respiratory, gastrointestinal, and ocular complications.

* * *

Analysis and Prevention of Data

that assess the Risk of Stevens-Johnson Syndrome and toxic epidermal necrolysis associated with nonsteroidal anti-inflammatory drugs.

[excerpted article, references omitted]

Final Report to Pharmacia, Inc.

Pharmacia Document Number: N49-00-07-850

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[10]

German Registry

In Germany, one NSAID diclofenac accounted for more than half of all prospectively ascertained cases of SJS/TEN occurring in outpatients and associated NSAID use within two weeks of onset (Table 4). However, diclofenac was by far the most frequently used prescription NSAID in Germany as measured by defined daily doses sold. Among NSAIDs with substantial use (>100 million defined daily doses), the oxicams and indomethecin had the highest point estimates of risk of SJS and TEN (Table 4). The risk of SJS and TEN was significantly higher for oxicams than that for diclofenac (RR=2.59, 95% CI=1.16 to 8.02). The risk of SJS and Ten were also significantly higher for the oxicams than ibuprofen (RR=3.05, 95% CI=1.16 to 8.02). Since our data included only prescription and not nonprescription use (available in Germany since 1989), the risk of ibuprofen is probably even lower relative to the oxicams than this ratio. The risk of SJS and TEN with oxicams carbamazepine and amoxicillin were not significantly different (RR=0.57, 95% CI=0.28-1.58) and (RR=0.45, 95% CI=0.19-1.04) for oxicams compared to carbamazepine and amoxicillin respectively.

Spontaneous Reports

From 1980 to 1997, the USFDA spontaneous reporting system recorded 2840 reactions coded as Toxic Epidermal Necrolysis, or Stevens-Johnson Syndrome with at least one drug suspected as the cause. Altogether, 3791 drugs were listed as suspect

agents for these 2840 reactions. More than 100 different drugs were listed as suspect agents for these reactions. The NSAIDs with the most reports [11] coded as SJS or TEN, (sulindac (89 reports)) ranked fifth among all drugs on the basis of total reports.

Of our comparator drugs, Cambazepine had slightly more reports than sulindac and more than twice as many reports with it as a suspect cause of SJS or TEN as piroxicam, the NSAID with the second largest number of reports. The number of reported cases of SJS and TEN with amoxicillin (N=45) and piroxicam (N=47) as a suspect drug as almost identical.

Of 14 NSAIDs marketed in 1997, we identified 10 that were listed suspect agents in at least 7 reports of SJS/TEN. Together these 10 NSAID medications were suspect in a total of 452 reported cases of SJS/TEN with represents ten percent of all cases in the FDA spontaneous report database we analyzed. For all 10 of these NSAIDs, the NAMCS estimates exceeded 5,000,000 visits to physicians with prescriptions for these agents between 1980 and 1997. The US marketed NSAIDs with fewer than 7 reactions (fenoprofen, meclofenamate, kelorolac and tolmetin) are excluded from all statistical analyses.

For the years 1980 to 1997, Table 5 provides the number of reports, number of visits with a prescription for the 10 NSAIDs with seven or more reported reactions. Data for carbamazepine and amoxicillin are also provided for comparison.

[12] The incidence of reports of SJS/TEN per million visits with a prescription for NSAIDs varied more than 20-fold from a high of 3.36 reactions per million prescriptions for diflunisal to 0.15 per million visits with a prescription for naproxen (including its sodium

salt) and excluding self medication of the over-the-counter form of this medication without a physician's advice. The number of SJS and TEN reports per year was significantly higher ($p<0.05$ for trend) in later years than earlier years (data not shown). The incidence of SJS/TEN reports per million visits with an NSAID prescription more than doubled from 1980-85 to 1994-97.

To adjust for increasing reporting rates overtime we use a Poisson model to calculate incidence rate ratios for reported reactions to NSAIDs and the two comparator drugs, using visits with a recommendation for use as our measure of exposure. We tested for statistically significant differences in incidence rate ratios between consecutively ranked drugs (ranked by incidence) (Table 6). We grouped drugs whose incidence was not significantly different from the drug with the next higher incidence together. By this criteria, these 12 drugs can be divided into 4 groups. As detailed in Table 6 among NSAIDs, diflunisal and sulindac have significantly and substantially higher rates of reports SJS/TEN reactions relative to office visits with a prescription than other NSAIDs. Two NSAIDs (ibuprofen and naproxen) have substantially and significantly lower reported reaction rates than other NSAIDs. Actual exposure for these two and

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[15]

Control Study and Germany Registry suggest tenoxicam and meloxicam have risks comparable to that for piroxicam. Data from both continents demonstrate Intermediate levels of risk for diclofenac and Indomethacin. Both European and US data suggest that naproxen has substantially lower risk

associated with its use than is the case for oxicams, diclofenac, and indomethacin. For ibuprofen, spontaneous US data suggest a very low risk relative to other NSAIDs marketed in the US. In contrast, the German registry and case control data suggest risks for ibuprofen that are comparable to that of diclofenac and as great as for most other non-oxicam NSAIDs. However OTC use is likely to have lead to an underestimate of exposure in our data. In the United States, two medications, diflunisal and sulindac appear to have higher reaction risks than other NSAIDs, but comparable data are not available for these medications from the European studies. In contrast to most of NSAIDs we assessed in our United States databases, sulindac prescriptions were more than three times more frequent in the 1980s than 1990s. Since 1991, the NAMCS data we analyzed indicates diflunisal prescribing has also substantially decreased. The differences in prescribing over time for these two drugs might have lead to inappropriate adjustment for time period in our analysis, but this explanation of the higher risk of these drugs seems unlikely.

In both the US spontaneous registry system and the case control study, incidence rates and relative risks varied more than 25-fold among NSAIDs. For all three studies the observed variability in risk among NSAIDs, which are [16] generally utilized for similar indications, further supports the hypothesis that the association of NSAIDs with a risk of SJS/TEN does not represent chance alone. When strength of association, quantity of data are available, and number of independent data sources that support our association are considered, the NSAIDs mot firmly linked to a substantial increase in SJS/TEN would appear to be the oxicams, diclofenac, and indomethicin. Sulindac is

a prominent cause of SJS and TEN in the US system, but this drug was not widely used in Europe in the 1990's. Sulindac also differed from other drugs in the temporal pattern of use and reports of SJS and TEN.

Although reporting and ascertainment biases or confounding by indications cannot be excluded as explanations for the highly significant association of use of some NSAID with SJS/TEN, there is apparent no reason to suspect these and other biases substantially impacted our calculation of relative risks among NSAIDs. Therefore, taken together our analyses are likely to provide robust assessments of the relative magnitude of risk of SJS/TEN associated with various NSAIDs.

Our ability to precisely determine absolute or excess risk of SJS and TEN in either short-term or long-term use of each agent is limited. For oxicams, the International Case Control Study predicts an excess risk of SJS/TEN of about 1 per million new users for each week of use during the first eight weeks of therapy. For the propanoic acid derivatives and diclofenac the excess of [17] SJS/TEN risk during the initial 8 weeks of use appears to be less than one tenth as high.

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[23]

Table 4
German Registry
Number of Cases of SJS/TEN, Defined Daily Doses, Incidence for NSAIDs 1992-1999*

	Cases*	Define Daily Doses (million)**	Incidence ***	
PIROXICAM	8	247	0.23	
MELOXICAM**	2	74	0.19	
IBUPROFEN	7	673	0.07	
KETOPROFEN	1	10	0.70	
DICLOFENAC***	31	2522	0.09	
NAPROXEN	2	54	0.25	
INDOMETHACIN	4	157	0.18	
CARBAMAZEPINE	35	632	- 0.38	
AMOXICILLIN	12	170	0.49	

* -Reactions developing in outpatients only and prospectively ascertained

** Includes prescription combination agents

*** Per 1,000,000 weeks of use based on defined daily doses

[24]

Table 5
US Food and Drug Administration Spontaneous Reports
of Stevens-Johnson Syndrome,
Toxic Epidermal Necrolysis, Out Patient Visits with Prescription and Incidence by Drug (1980 – November 1997)

	Cases	Visits with Prescription (millions)	Incidence*
CARBAMAZEPINE	119	18.5	6.44
DIFLUNISAL	33	9.8	3.36
SULINDAC	89	30.8	2.89
OXAPROZIN	15	8.3	1.80
PIROXICAM	47	36.6	1.29
ETODOLAC	7	8.6	0.81
DICLOFENAC	31	40.5	0.77
NAMBUTONE	13	19.8	0.66
IDOMETHACIN	14	40.0	0.35
IBUPROFEN	27	159.3	0.17
NAPROXEN	27	135.9	0.15
AMOXICILLIN	45	44.4	0.11

* Per million visits with prescription or advice to use.

[25]

Table 6

Adjusted Incidence Rate Ratio and 95% Confidence Interval of NSAIDs and Select Other Drugs Adjusted for Data of Report and Ranking Unadjusted. For USFDA Spontaneous Reports of SIS/TEN (1980-November 1987)

	IRR	95% Confidence For Interval	Rank (Unadjusted)	Rank NSAID only	Group*
CARBAMAZEPINE	.1		1	-	1
DIFLUNISAL	.56	0.38-0.83	4	1	1
SULINDAC	.58	0.44-0.77	5	2	1
OXAPROZIN	.23	0.13-0.41	7	3	2
PIROXICAM	.21	0.15-0 29	8	4	2
ETODOLAC	.13	0.05-0.28	10	5	3
DICLOFENAC	.11	0.07-0 16	11	6	3
NAMBUTONE	09	0 05-0 16	12	7	3
INDOMETHACAN	.07	0.04-0.11	13	8	3
IBUPROFEN	.03	0.02-0.04	14	9	4
NAPROXEN	.02	0.01-0.03	15	10	4
AMOXICILLIN	.02	0.01-0.02	16	-	4

* After ranking by adjusted incidence, groups were determined by comparing incidence of a given drug with that drug with next lower incidence. If incidence was significantly lower than a new group number was assigned, if not both drugs were assigned to the same group.

Comparison of Reporting of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Association with Selective COX-2 Inhibitors

[excerpted article, references omitted]

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Abstract

Background: Stevens-Johnson syndrome and toxic epidermal necrolysis are closely related severe acute life-threatening, drug-induced skin disorders. The US FDA Adverse Events Reporting System (AERS) has received reports of Stevens-Johnson syndrome and toxic epidermal necrolysis associated with the use of the recently introduced selective cyclo-oxygenase (COX)-2 inhibitor NSAIDs, two of which are also sulfonamides.

Objective: The objective of this study is to review cases of Stevens-Johnson syndrome and toxic epidermal necrolysis reported to the FDA associated with the use of the selective COX-2 inhibitor NSAIDs celecoxib, rofecoxib and valdecoxib, and to compare reporting rates of the two conditions associated with these drugs to each other, meloxicam (an oxicam NSAID that came on the US market at a similar time) and the background incidence rate.

Methods: We reviewed all US cases of Stevens-Johnson syndrome and toxic epidermal necrolysis reported to the FDA AERS database associated with the use of celecoxib rofecoxib, valdecoxib and meloxicam since these agents were first marketed. We

utilised AERS and drug use data to calculate reporting rates for each drug after the first 2 years of marketing. We obtained the background rate from the medical literature.

Results: Up to the end of March 2004, there were 63 cases of Stevens-Johnson syndrome/toxic epidermal necrolysis reported with valdecoxib use, 43 with celecoxib, 17 with rofecoxib (the non-sulfonamide coxib) and none for meloxicam. In the first 2 years of marketing the reporting rate for Stevens-Johnson syndrome/toxic epidermal necrolysis with valdecoxib was 49 cases per million person-years of use, 6 cases per million person-years for celecoxib and 3 cases per million person-years for rofecoxib. The reporting rates for the sulfonamide coxibs were substantially higher than the background rate of 1.9 cases per million population per year, with the valdecoxib rate being 8-9 times that of celecoxib and approximately 25 times that of the background rate.

Conclusion: There is a strong association between Stevens-Johnson syndrome/toxic epidermal necrolysis and the use of the sulfonamide COX-2 inhibitors, particularly valdecoxib. Physicians should be aware of the possibility of this [918] serious life-threatening event when prescribing these drugs and advise patients to discontinue use at the earliest possible sign or symptom.

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[922]

factor is not clear. For some patients, it could be a risk factor and certainly a history of sulfa allergy should be a contraindication for use of either of the two sulfonamide coxibs.

The strength of spontaneous reporting systems is that they are a cost-effective method if detecting rare, unexpected adverse reactions to drugs. So they are ideal for detecting a signal like Stevens-Johnson syndrome or toxic epidermal necrolysis, which are rare disorders with an estimated background rate of 1-2 cases per million population per year. However, spontaneous reporting systems are subject to a number of important limitations. Reports may be incomplete, with missing demographic and other data. More importantly, there is usually substantial under-reporting of adverse events. Mittman and colleagues recently examined the problem of under-reporting of toxic epidermal necrolysis in a Canadian population and found that 4-10% of cases were actually reported. Factors believed to affect the likelihood of reporting include event severity, whether the event is labeled or not, publicity surrounding the event or the drug and secular patterns related to the time of marketing and length of time on the market, among others. These factors often affect reporting to varying extents for different drugs. For this reason reporting rates cannot be equated with incidence rates.

Spontaneous reporting systems are not designed to assess causality but can highlight associations between particular drugs and adverse events. The exact number of events that constitutes a signal varies with the rarity and seriousness of the event. Stevens-Johnson syndrome and toxic epidermal necrolysis are extremely rare disorders and are almost always drug induced. For these reasons, we believe there is a causal association in our series between valdecoxib use and serious skin reactions.

To minimise the potential biases described previously, we used two other coxibs marketed at about the same time, celecoxib and rofecoxib, as comparators for valdecoxib. We limited comparison to the first 2 years on the market because studies have shown that adverse events are more likely to be reported early in marketing. Because celecoxib is also a sulfonamide and is marketed in the US by the same company as valdecoxib, there was a lower likelihood of reporting differences between these products. We chose meloxicam as a comparator for the coxib group because it is a traditional NSAID with COX-2 selectivity and is used for a similar indication to the coxibs. Also, meloxicam was first marketed in the US in April 2000, in the same general time period as the coxibs. There were no cases reported in AERS associated with meloxicam, perhaps because usage in the US was very low (table II).

Our comparison showed that the reporting rate was higher for both sulfonamide coxibs than for rofecoxib and meloxicam; however, this difference was substantially higher for valdecoxib and even more so when compared with the background rate for Stevens-Johnson syndrome/toxic epidermal necrolysis of 1-2 cases per million population per year. That the reporting rate for Stevens-Johnson syndrome/toxic epidermal necrolysis with valdecoxib was 26 times that for the background incidence rate is notable, given the likely 10-fold under-reporting of this event. The actual incidence is likely to be much higher. The 9-fold difference between valdecoxib and celecoxib suggests that being a sulfonamide does not solely account for this difference.

We are usually hesitant to apply statistical tests to spontaneous reports data as the variance structure of such data is undefined. Nevertheless, because of the magnitude of the signal with valdecoxib, we calculated confidence intervals for the reporting rates. The absence of overlap between the confidence intervals for valdecoxib is distinctly different from the other coxibs with respect to the risk of Stevens-Johnson syndrome and toxic epidermal necrolysis.

At present there is no satisfactory method for determining who is at greatest risk for developing drug-associated Stevens-Johnson syndrome and toxic epidermal necrolysis and hence of preventing it, short of avoiding drugs altogether. There has been a single study suggesting that early withdrawal of the agent at the first sign of the illness may improve the outcome. Although this intuitively makes [923] sense, this study needs to be replicated.

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PETITIONER'S BRIEF

No. 12-142

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF PETITIONER MUTUAL PHARMACEUTICAL COMPANY, INC.

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QUESTION PRESENTED

Whether the First Circuit erred in holding that federal law does not preempt state law design-defect claims targeting generic drug products because the conceded conflict between such claims and the federal laws governing generic drug design allegedly can be avoided if the makers of generic drugs simply stop selling their products.

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rules 24.1(b) and 29.6, Petitioner Mutual Pharmaceutical Company, Inc. ("Mutual") incorporates the corporate disclosure statement contained in its previously filed Petition for Writ of Certiorari.

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INTRODUCTION

This case is controlled by a straightforward application of *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Two terms ago, that decision foreclosed state-law claims targeting generic drugs because the Hatch-Waxman Act imposes "an ongoing federal duty of sameness" that precludes generic drugs from deviating in any material respect from their brand-name equivalents. *Id.* at 2574-75 (internal quotation omitted). With the exception of the First Circuit's outlier decision in this case, literally dozens of courts thus have rejected lawsuits targeting generic drugs based on *Mensing*'s sameness rationale: Regardless of whether a state tort claim is captioned "failure to warn," "design defect," or something else entirely, these courts have recognized that the Constitution requires state law to yield if it would obligate a generic drug manufacturer to violate the federal sameness mandate as a precondition to engaging in interstate commerce.

The First Circuit was undeterred. It initially asserted that *Mensing* was limited to failure-to-warn claims, and thus did not implicate design-defect claims. PA10a-11a.[1] But the appellate court soon conceded that Hatch-Waxman's federal sameness mandate—and thus *Mensing*'s sameness rationale—

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[1] Citations to the PA reference the appendix accompanying Mutual's petition. Citations to the SPA reference the supplemental appendix accompanying Mutual's reply to respondent's brief in opposition. Citations to the JA reference the joint appendix. Citations to the CAA reference Mutual's First Circuit appendix.

applies equally to generic drug design and generic drug labeling. PA10a ("[T]he generic maker also cannot alter the composition of the drug."). And it recognized that failure-to-warn and design-defect claims equally thwart Congress's manifest intent to promote the sale of generic drugs. *Id.* ("[*Mensing*] held that Congress cannot have wanted the generic to pay damages under state law for a label that the FDA required. Mutual argues with some force that the generic maker also cannot alter the composition of the drug and so [Congress]'s policy of encouraging generics by preempting state tort claims should extend to design defect as well as [warning] claims.").

Even so, the appellate court held that respondent's state law design-defect claim did not conflict with Hatch-Waxman's sameness mandate, and thus survived *Mensing*'s preemption holding, because Mutual "certainly can choose not to make the drug at all." *Id*; PA10a-11a ("[T]he decision to make the drug and market it in New Hampshire is wholly [Mutual's] own.").

That is no answer. The *Mensing* defendants likewise were free not to make or market their drugs, and *Mensing* found preemption even though the Eighth Circuit had advanced this same "stop-selling" theory in the decision this Court reversed. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009) [*Mensing I*] ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient ... they could have simply stopped selling the product."). Were the First Circuit's decision correct, *Mensing* thus would have come out the other way—as the court again conceded. PA11a ("[A] generic maker can avoid

defective warning lawsuits as well as design defect lawsuits by not making the drug.").

Nor is it any wonder why *Mensing* failed to embrace the Eighth Circuit's stop-selling rationale. This Court long ago recognized that state tort claims embody substantive state-law duties, and that tort verdicts like the one here thus establish that the defendant violated a state-law requirement. *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992) (plurality). Where the substantive state-law requirement embodied by a given tort claim conflicts with a contrary federal requirement, the ordinary operation of the Supremacy Clause prevents the state from enforcing its conflicting demand; were it otherwise, federal law no longer would be "the supreme Law of the Land." U.S. CONST. art. VI, cl. 2.

Contrary to the First Circuit's apparent belief, the stop-selling end-run does not avoid such conflicts. It only underscores that it is impossible for the manufacturer of a federally regulated product to fulfill its substantive federal and state obligations simultaneously, and ensures that state law prevails every time by letting juries impose liability *precisely because* the defendant complied with controlling federal standards from which it could not deviate without violating federal law. If the Supremacy Clause does anything, it forecloses this radical approach: Because every manufacturer can "choose" to stop making any product, no federal requirement ever could generate a direct preemptive conflict in a stop-selling world. *Mensing* rejected similar efforts to write ordinary conflict preemption out of the

Constitution, and there is no reason for departing from that decision here. 131 S. Ct. at 2579 ("We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless.").

Ultimately, it is hard to imagine a result more at odds with Hatch-Waxman than this one. Even if the stop-selling theory could escape direct conflict preemption under *Mensing*, it wholly undermines the federal regime. Congress designed Hatch-Waxman to ensure that generic copies of previously approved drugs are available for sale whenever their costly branded equivalents come off patent; as *Mensing* said, "it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public." 131 S. Ct. at 2582.

State-law verdicts that effectively order generic drugs withdrawn from interstate commerce *because* they complied with the federal sameness mandate eviscerate that core statutory objective. Indeed, such verdicts are particularly troubling today, when spiraling healthcare costs and concerns about growing federal deficits make Hatch-Waxman's goal of promoting price competition more important than ever before. And, finally, the stop-selling theory undercuts Congress's specific delegation to FDA of continually expanding authority to order approved drugs withdrawn from interstate commerce in the exercise of its expert judgment and subject to specific statutory protections for parties aggrieved by such orders. In sum, the stop-selling theory undercuts both Hatch-Waxman and the broader FDCA regime.

The decision should be reversed.

OPINIONS BELOW

The First Circuit's opinion is reported at 678 F.3d 30 and reprinted at PA1a-24a. The appellate court's errata is reprinted at PA27a-28a. The district court's opinion denying petitioner's renewed motion for judgment as a matter of law is reported at 760 F. Supp. 2d 220 and reprinted at PA29a-103a. The district court's opinion partially granting and partially denying petitioner's motion for summary judgment is reported at 731 F. Supp. 2d 135 and reprinted at PA106a-141a. The district court's unpublished order and opinion denying petitioner's motion for judgment on the pleadings is available at 2010 WL 3659789 and reprinted at PA142a-202a.

JURISDICTION

The First Circuit issued its decision and judgment on May 2, 2012, PA25a-26a, and the petition was timely filed on July 31, 2012. This Court has jurisdiction under 28 U.S.C. § 1254(1).

PERTINENT CONSTITUTIONAL AND STATUTORY PROVISIONS

The Constitution's Supremacy Clause provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. CONST. art. VI, cl. 2.

The pertinent portions of the Federal Food, Drug, and Cosmetic Act are reproduced in Addendum A to this brief.

STATEMENT OF THE CASE

A. Statutory Background

1. The Statutory Scheme Before 1984

For nearly 75 years, the Federal Food, Drug, and Cosmetic Act ("FDCA") has governed the terms under which pharmaceutical products can be both marketed in and ordered withdrawn from interstate commerce. When Congress enacted the original FDCA in 1938, it for the first time required manufacturers to obtain FDA approval before selling a new drug. Pub. L. No. 75-717, ch. 675, § 505(a), 52 Stat. 1040, 1052 (1938) [the "1938 Act"] ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to [this Act] is effective with respect to such drug.").

To that end, the 1938 Act required applicants to submit to FDA an application that included (1) reports of clinical studies showing that "such drug is safe for use;" (2) a listing of all "components of such drug;" (3) a "statement of the composition of such drug;" (4) a description of "the methods ... facilities and controls used for ... manufactur[ing], processing, and packing" the drug; (5) samples of the product and its components to the extent "the Secretary may require," and (6) proposed labeling for the drug. 1938 Act § 505(b), 52 Stat. at 1052. The Act in turn granted FDA broad authority to deny interstate marketing approval whenever it found a proposed drug would be unsafe, *id.* §505(d), 52 Stat. at 1052,

but presumed approvability by providing that applications would be deemed approved if the Agency did not reject them within 60 (or, in some cases, 180) days. *Id.* § 505(c), 52 Stat. at 1052.

The 1938 Act also directed FDA to determine when previously approved drugs should be removed from interstate commerce. It directed FDA to:

> suspend ... [t]he effectiveness of an application with respect to any drug ... if the [Agency] finds that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use.

Id. § 505(e), 52 Stat. at 1053 (enumeration omitted).

Not surprisingly, the law granted manufacturers significant protections in cases where FDA sought to exercise its new suspension authority. *First*, it provided that FDA could suspend interstate marketing approval only after providing the manufacturer with "due notice and opportunity for hearing." *Id.* *Second*, it required FDA to issue a written suspension "order [that] shall state the findings upon which it is based." *Id.* *Finally*, it provided aggrieved parties with a right to judicial review of any suspension decision in federal district court based on "the record [giving rise to] the order." *Id.* § 505(h), 52 Stat. at 1053.

Congress substantially expanded FDA's authority in 1962 by requiring it to consider drug efficacy in making approval and withdrawal decisions. Drug Amendments of 1962 [the "1962 Act"], Pub. L. No. 87-781, § 102(c), 76 Stat. 780, 781 (compelling FDA

to reject applications which "lack ... substantial evidence that the drug will have the effect it purports or is represented to have"); *id.* § 102(d), 76 Stat. at 781-82 (requiring FDA to "withdraw approval ... if [it] finds ... a lack of substantial evidence that the drug will have the effect it purports or is represented to have").

The 1962 Act also repealed the *de facto* presumption that drugs were approvable; it now required *actual* FDA approval of a New Drug Application ("NDA") before interstate sales could commence. *Id.* § 104(a), 76 Stat. at 784 (barring the sale of any drug in interstate commerce "unless *an approval of* an application ... is effective with respect to such drug") (emphasis added). And it bolstered FDA's authority to order approved drug products off the market by empowering the Agency to revoke interstate marketing approval in an array of new circumstances. *Id.* § 102(d), 76 Stat. at 781-82 (permitting, but not requiring, FDA to withdraw marketing approval based on recordkeeping failures; manufacturing, processing, and packing deficiencies; and labeling deficiencies).

Finally, the 1962 Act made two changes to the protections previously granted parties aggrieved by FDA's withdrawal authority. *First*, where FDA sought to exercise its permissive withdrawal authority, the statute required FDA to provide both "written notice ... specifying the matter complained of" and an opportunity to correct the specified deficiencies "within a reasonable time" even before the Agency could proceed to notice and hearing on an actual withdrawal decision. *Id.* *Second*, Congress transferred judicial review of withdrawal orders from

the federal district courts to the federal appellate courts. *Id.* § 104(d)(1), 76 Stat. at 784.

2. The Hatch-Waxman Act

The early versions of the FDCA generally applied with equal force to all drugs—branded and generic alike. Virtually every manufacturer thus was required to submit an NDA that included its own safety and efficacy studies to secure and maintain interstate marketing approval. FDA, *Abbreviated New Drug Application Regulations—Final Rule* ["*Final ANDA Rule*"], 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992). That meant that even after the patents protecting a branded drug expired, virtually no generic copy could be approved until its manufacturer replicated the brand manufacturer's prior clinical studies.[2]

This had two consequences. *First*, the brand manufacturer benefited from a *de facto* extension of its patent monopoly. The patent laws at that time prevented generic companies from beginning clinical

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[2] There were two exceptions: FDA's so-called "DESI" regulation and its controversial "paper NDA" process. Under the DESI regulation, applicants could "submit information [to FDA] that showed the applicant's ability to manufacture a product ... whose safety and effectiveness were equivalent to [a pre-1962] drug product whose safety and effectiveness had been established." *Final ANDA Rule*, 57 Fed. Reg. at 17950. The paper NDA process "permitted FDA to approve NDA's for post-1962 drug products [based on] safety and effectiveness information derived primarily from published reports based on well-controlled studies. This meant that manufacturers did not have to conduct their own tests, but adequate literature [to support approval] was [rarely] available." *Id.* at 17951.

studies until patent expiry, and those studies—once initiated—took years to complete. Laura J. Robinson, *Analysis of Recent Proposals to Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 52 (2003). Branded companies thus could maintain high prices long after patent expiry theoretically had opened the door to competition. *Second*, the extraordinary costs of conducting clinical studies were reflected in generic prices—meaning that the price of *all* drugs remained considerable even after competition began.

Not surprisingly, FDA approved few duplicate drugs under this regime; given the clinical trial requirements and the limited utility of the DESI and paper NDA processes, it simply was not cost-effective to develop and market generic drugs. In 1984, generics thus filled less than 19 percent of all prescriptions, Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993 (2007), and hundreds of widely prescribed branded drugs lacked any generic equivalent. FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, at 4 (July 2002), *available at* http://tinyurl.com/FTCStudy.[3]

By the early 1980s, Congress recognized that millions of Americans were unable to afford both the basic necessities of life and essential medications. It also recognized that state and federal authorities were wasting billions of dollars on costly branded drugs whose patent protection had expired. To remedy those problems and thereby "get generic

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[3] All websites were visited and verified on January 13, 2013.

drugs into the hands of patients at reasonable prices—fast," Republican Senator Orrin Hatch and Democratic Representative Henry Waxman labored for years to establish an expedited approval pathway for generic drugs. *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quotation omitted); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) ("[T]he purposes of the legislation are 'to make available more low cost generic drugs,'" and "'provide regulatory relief, increase competition, economy in government, and best of all, [allow] the American people [to] save money, and yet receive the best medicine that pharmaceutical science can provide.'") (quoting *inter alia* Statement On Signing S. 1538 Into Law, 20 Weekly Comp. Pres. Doc. 1359, 1360 (Sept. 24, 1984)).

The resulting Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Sept. 24, 1984)—more commonly known as the Hatch-Waxman Act—for the first time drew sharp distinctions between branded and generic drugs. While companies seeking to market an innovative drug product must continue to submit full NDAs (including clinical trial reports), *Mensing*, 131 S. Ct. at 2574 (citing 21 U.S.C. §§ 355(b)(1), (d)), applicants seeking to market copies of those drugs file only an Abbreviated New Drug Application ("ANDA") demonstrating the product's chemical and biological equivalence to a previously approved drug (called the "reference listed drug"). *Id.* (citing 21 U.S.C. § 355(j)(2)(A)).

To that end, the statute requires ANDA applicants to demonstrate that a proposed generic

drug is identical to its branded equivalent in all material respects—that is, that the generic product has the same design as its branded predecessor. ANDA applicants therefore must prove that the proposed generic drug contains "*the same*" active ingredient(s); employs "*the same*" route of administration (*e.g.*, oral or injected); presents "*the same*" dosage form (*e.g.*, tablet or capsule); exhibits "*the same*" strength (*e.g.*, 20mg or 40mg); and is "bioequivalent"[4] to its branded counterpart, in order to ensure it will "have *the same* therapeutic effect" as the branded equivalent. 21 U.S.C. § 355(j)(2)(A)(i)-(iv) (emphases added)[5]; *Mensing*, 131 S. Ct. at 2574 n.2 (explaining that each generic drug must be "*identical* [to its branded equivalent] in *active ingredients, safety, and efficacy*") (emphasis added).[6]

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[4] Generally speaking, two drugs are considered bioequivalent if there is "[no] significant difference in the rate and extent to which the active ingredient ... becomes available at the site of action when administered at the same molar dose under similar conditions." 21 C.F.R. § 320.1(e).

[5] Unless otherwise noted, all citations to 21 U.S.C. § 355 are to the 2004 version of the statute, in place at the time of the events giving rise to this case.

[6] The statute does not require generic drugs to include the same *inactive* ingredients as the branded equivalent and thus empowers FDA to deny approval where "the inactive ingredients ... are unsafe ... or the composition of the drug is unsafe ... because of the type or quantity of inactive ingredients included or the manner in which the[y] are included." 21 U.S.C. § 355(j)(4)(H) (enumeration omitted). The statute also allows applicants to petition FDA for permission to submit an ANDA "for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength

The net result of those requirements is that generic product design must be materially identical to that of its branded counterpart—which explains why, as *Mensing* recognized, generic product labeling must also be "'the same as the labeling approved for the [brand-name] drug.'" *Mensing*, 131 S. Ct. at 2574 (quoting 21 U.S.C. § 355(j)(2)(A)(v); citing *id.* § 355(j)(4)(G) (alteration in original)); *Final ANDA Rule*, 57 Fed. Reg. at 17961 ("[T]he ANDA product's labeling must be the same as the listed drug product's labeling *because* the listed drug product is the basis for ANDA approval.") (emphasis added).

There is no question that Hatch-Waxman has been wildly successful: By using the sameness mandate to streamline generic entry into interstate commerce and thereby expand access to affordable generic drugs, Hatch-Waxman has saved consumers literally trillions of dollars since enactment. *Mensing*, 131 S. Ct. at 2582 ("[I]t is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public."); HHS, *ASPE Issue Brief: Expanding the Use of Generic Drugs*, at 6 (Dec. 1, 2010), *at* http://tinyurl.com/HHSStudy ("[S]avings from the use of generic drugs for the total healthcare system were estimated to be $139.6 billion in 2009 [alone].").

B. The *Mensing* And *Demahy* Cases

Despite Hatch-Waxman's longstanding sameness requirement for generic drugs, its effect on state tort

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differ from that of a listed drug." *Id.* § 355(j)(2)(c). Neither exception to the sameness requirement is relevant here.

claims targeting generic drugs was unsettled until 2011, when this Court consolidated two cases for decision and held that Hatch-Waxman's sameness requirement preempts state-law tort claims targeting generic drugs.

In *Mensing* and *Demahy*, both plaintiffs alleged injuries resulting from metoclopramide, the generic version of branded Reglan®. Their complaints each included an array of state tort claims against the generic drug manufacturers, including strict liability for both failure to warn *and* design defect. First Am. Compl. ¶¶106-115, *Mensing v. Wyeth, Inc.*, No. 07-cv-3919 (D. Minn. filed Feb. 22, 2008); Compl. ¶¶37-42, *Demahy v. Wyeth*, No. 2:08-cv-03616-CJB-JCW (E.D. La. filed on removal June 2, 2008).

The generic manufacturers in *Mensing* moved to dismiss the plaintiff's complaint in its entirety as preempted by Hatch-Waxman's sameness mandate, and the district court—after explaining that all claims, including design defect, were "essentially 'failure to warn' claims"—granted the motion. *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1061 n.6 (D. Minn. 2008) ("[A]ll of Plaintiff's claims ... are encompassed by the Court's preemption analysis.").

The Eighth Circuit reversed. It acknowledged that the federal sameness mandate prohibits manufacturers from altering generic drug warnings, but held the defendants could have complied with state law without violating that rule by asking FDA to authorize new warnings. *Mensing I*, 588 F.3d at 608-10. And it declared that state tort claims would not conflict with federal law even if that option was not available:

> The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product.... If Mensing's injuries resulted ... they may be held liable.

Id. at 611.

While *Mensing* unfolded in Minnesota, *Demahy* was proceeding in federal court in Louisiana. As in *Mensing*, the generic manufacturer moved on preemption grounds to dismiss Demahy's lawsuit in its entirety, but this time the court denied the motion. *Demahy v. Wyeth, Inc.*, 586 F. Supp. 2d 642 (E.D. La. 2008). The Fifth Circuit then affirmed on interlocutory review, echoing the Eighth Circuit's assertion that the defendant at least could have discussed labeling changes with FDA, and further asserting that the sameness requirement applies only before FDA approval (leaving generic companies free to alter their labeling post-approval through the so-called "Changes Being Effected" or "CBE" process). *Demahy v. Actavis, Inc.* [*Demahy I*], 593 F.3d 428, 436-46 (5th Cir. 2010).

This Court granted *certiorari* in both cases and reversed—holding without qualification that "federal law pre-empts *these lawsuits*." *Mensing*, 131 S. Ct. at 2581 (emphasis added). The Court first rejected *Demahy*'s assertion that generic companies can use the CBE procedure to deviate from the branded product labeling after approval, because Hatch-Waxman's sameness requirement applies at all times. *Id.* at 2575-76. It next rejected the plaintiffs' contention that the generic manufacturers could

have sent "Dear Doctor letters" to healthcare practitioners without a corresponding letter from the brand manufacturer, since that "would inaccurately imply a therapeutic difference between the brand and generic drugs." *Id.* at 2576.

Finally, this Court refused to allow claims that the generic manufacturers at least could have "taken steps" to change their labeling by alerting FDA to the need for stronger warnings. *Id.* at 2579-82. Even though federal law permitted the defendants to do so, the Court rejected these claims because FDA would have had to authorize the new warnings before the defendants could have implemented them. *Id.* at 2581. Ultimately, the Court held the plaintiffs' lawsuits were preempted in their entirety: "[B]ecause pharmacists, acting in full accord with state law, substituted generic metoclopramide [for brand-name Reglan®], federal law pre-empts these lawsuits." *Id.* (citations omitted).

The plaintiffs then petitioned for rehearing, reiterating the Eighth Circuit's earlier assertion that the defendants could have complied with both the federal sameness mandate and their state-law tort duties *without* requiring FDA's involvement:

> Petitioners could have satisfied their duty under state tort law by suspending sales of the product with a label that they knew or should have known was inadequate. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009). That course of action was always available to them and could have been accomplished independently, without any action by the FDA.

Resps.' Pet. for Reh'g, *Mensing*, 2011 WL 2874547, at *2 (July 18, 2011) (parenthetical omitted); *see also id.* at *1 ("The Court overlooks ... that the Petitioner[s] could have independently complied with both state and federal law simply by suspending sales of generic metoclopramide.") (quotation omitted). This Court denied rehearing. *Actavis Elizabeth, LLC v. Mensing*, 132 S. Ct. 56 (2011); *PLIVA, Inc. v. Mensing*, 132 S. Ct. 55 (2011).

C. Facts and Proceedings

1. Sulindac

Sulindac is a non-steroidal anti-inflammatory drug ("NSAID") indicated for acute or long-term use in relieving the signs and symptoms of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, acute painful shoulder (subacromial bursitis/supraspinatus tendinitis), and acute gouty arthritis. JA553. FDA first approved sulindac for sale in September 1978, and Merck & Co., Inc. ("Merck") began marketing it as brand-name Clinoril®.

In May 1987, Mutual filed ANDAs seeking FDA approval to market generic sulindac, and FDA approved Mutual's products for interstate commercial sale on April 17, 1991 after finding them "safe and effective for use." CAA2169. There is no dispute that Mutual's sulindac is, and always has been, chemically and bioequivalent to Clinoril®, and that Mutual's sulindac labeling was materially identical to Clinoril®'s labeling. On October 22, 2002, FDA approved Mutual's request to conform its labeling to mirror changes in the Clinoril® labeling. CAA2171. That labeling was operative at all times relevant here, and repeatedly warned that sulindac therapy was associated with a rare but potentially

life-threatening dermatologic reaction known as Stevens-Johnson Syndrome and toxic epidermal necrolysis ("SJS/TEN"):

WARNINGS

***

Hypersensitivity

Rarely, fever and other evidence of hypersensitivity (*see ADVERSE REACTIONS*) *including ... severe skin reactions* have occurred during therapy with sulindac. *Fatalities have occurred in these patients.... If unexplained fever or other evidence of hypersensitivity occurs, therapy with sulindac should be discontinued.*

***

ADVERSE REACTIONS

***

Dermatologic...

Erythema multiforme, toxic epidermal necrolysis, Stevens-Johnson syndrome, and exfoliative dermatitis have been reported.

***

Hypersensitivity Reactions...

A potentially fatal apparent hypersensitivity syndrome has been reported. This syndrome may include constitutional symptoms..., *cutaneous findings (rash or other dermatologic reactions—see above),* conjunctivitis, involvement of major organs ..., and other less specific findings.

JA553-554 (emphases added). There is no dispute that SJS/TEN is exceptionally rare; respondent's own expert testified that it occurs only in "one to two [people] per million." JA424.

In April 2005, FDA recommended that all NSAID manufacturers implement certain labeling changes. *See* FDA, COX-2 Selective (Includes Bextra, Celebrex, and Vioxx) and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) ["FDA Request"], *at* http://tinyurl.com/NSAIDRequest. Consistent with FDA's request, Merck amended its Clinoril® labeling to include an additional warning regarding adverse dermatologic reactions (including SJS/TEN), and Mutual followed suit. JA555-556.

FDA also requested that NSAID manufacturers add a so-called "black box warning" regarding certain cardiovascular and gastrointestinal risks. *See* FDA Request. Those changes are irrelevant here, except that FDA (1) expressly considered and rejected adding language about SJS/TEN to the requested black box, and (2) reiterated its determination that NSAIDs other than Bextra® should remain available for sale in interstate commerce despite their known association with SJS/TEN. JA579-581 & n.8 (observing that "[w]hile other COX-2 selective and non-selective NSAIDs also have a risk for these rare, serious skin reactions, the reported rate for these serious side effects appears to be greater for Bextra"; concluding that only Bextra® had a sufficiently adverse risk/benefit profile to warrant withdrawing the product from interstate commerce; and observing that "[t]he risk for serious skin reactions is already included in the labeling for most [other] prescription NSAIDs").

FDA maintains its approval of both Merck's Clinoril® and Mutual's generic sulindac to this day.

2. Respondent's Use Of Sulindac

In December 2004, respondent Karen Bartlett sought treatment for acute shoulder pain. Her orthopedist prescribed Clinoril®, and her pharmacist eventually dispensed Mutual's generic sulindac pursuant to New Hampshire law. PA3a; *see also* N.H. Rev. Stat. Ann. § 318:47-d (2003) (allowing generic substitution). In 2005, respondent developed an especially severe case of SJS/TEN. PA3a.

There is no question that the results were horrific. Respondent suffered burns and burn-like wounds covering nearly two-thirds of her body. PA23a. Subsequent treatment required respondent to spend months in a medically-induced coma and undergo repeated eye surgeries. PA22a-23a. She now suffers from an array of permanent disabilities; she "cannot eat normally due to esophageal burns, cannot have sexual relations due to vaginal injuries, and cannot engage in aerobic activities due to lung injuries. She is almost blind now and faces some likelihood of complete and permanent blindness. She cannot read or drive or work. And she is seriously disfigured in face and body." PA23a.

3. Pretrial Proceedings

On January 8, 2008, respondent sued Mutual in New Hampshire state court. PA1a-4a. As in *Mensing* and *Demahy*, respondent's complaint raised an array of state-law claims—including both failure-to-warn and design-defect claims, JA57-80—and Mutual moved for judgment on the pleadings after removing the case to federal court. As Mutual

explained, federal law preempted the lawsuit both because it was impossible for Mutual to comply with Hatch-Waxman's sameness requirement and the alleged state-law duties, and because respondent's state-law claims otherwise frustrated Hatch-Waxman's goal of ensuring the sale of low-cost generic drugs. Mem. In Supp. of Mot. for J. on the Pleadings, 2008 WL 7027516, at 5-22 (Dec. 3, 2008).

The district court rejected Mutual's preemption defense on September 30, 2009. It began by effectively conceding that federal law precluded Mutual from altering the design of its generic product. PA165a-166a. It nonetheless rejected Mutual's preemption defense as to respondent's design-defect claim, reasoning that "[w]hile one way to avoid violating state law ... would be to redesign Sulindac..., another way to do so would be to refrain from distributing it at all." PA165a. Because Hatch-Waxman did not compel Mutual to sell its FDA-approved product, the court asserted that there was no conflict between federal law and respondent's design-defect claim. PA165a-166a.

The court next rejected Mutual's argument that respondent's failure-to-warn claims were preempted. Like the Fifth Circuit's erroneous decision in *Demahy I*, the district court asserted that federal law did not prevent Mutual from unilaterally altering its labeling following FDA approval because Hatch-Waxman's sameness requirement allegedly applies only before approval. PA168a-197a. Finally, the court rejected Mutual's argument that respondent's state-law claims impermissibly undermined Hatch-Waxman's purposes and objectives. PA198a-202a.

Discovery followed, and Mutual eventually filed two motions for summary judgment. Mem. In Supp. of Summ. J. Based on Fed. Preemption ["Preemption MSJ"], 2010 WL 1371985 (Mar. 30, 2010); Mem. In Supp. of Summ. J. ["Causation MSJ"], 2010 WL 1371986 (Mar. 30, 2010). The first motion reiterated Mutual's earlier preemption arguments regarding the sameness requirement for generic drug labeling and, consistent with comment k to *Restatement (Second) of Torts* § 402A (1965), further explained that there is no distinction between failure-to-warn and design-defect claims for preemption purposes because "drugs are unavoidably unsafe products, and as such, cannot be defective in design as long as they are accompanied by adequate warnings." Preemption MSJ, 2010 WL 1371985, at 31-32; *see also Restatement (Second) of Torts* § 402A (1965), cmt. k ("There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs.... Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous."). The district court treated the motion as one for reconsideration, PA139a, and denied it largely for the reasons it previously expressed. PA140a.

Mutual's second summary judgment motion argued that respondent's claims failed for lack of causation because discovery had revealed that respondent's prescribing physician never even read Mutual's labeling. Causation MSJ, 2010 WL 1371986, at 8-16. That meant *all* of respondent's claims were barred, since each depended on the alleged inadequacy of Mutual's FDA-mandated

warnings and since her physician's failure to read those warnings meant respondent's injuries could not have been caused by any alleged deficiency in the warnings. *Id.* at 17-20.

On July 12, 2010, the district court dismissed respondent's failure-to-warn claims on the foregoing causation grounds. PA117a-121a. But it denied Mutual's motion with respect to design defect, conceding that such claims necessarily turn on the adequacy of a drug's warnings, but asserting that the adequacy of petitioner's FDA-mandated labeling—which, again, respondent's physician never even read, and which Mutual repeatedly had explained it could not change—remained an issue for trial. PA124a-128a.

Respondent's remaining state-law claims then were dismissed either by court order (on various non-preemption grounds) or voluntarily. PA4a-5a.

4. Trial Proceedings

Those developments left only respondent's straight liability design-defect claim intact, and trial began in August 2010. Any possibility that trial would proceed as something other than a standard failure-to-warn case quickly evaporated. Although Mutual had withdrawn its comment k defense "for purposes of the trial of this matter," Notice of Withdrawal of Defenses, Dkt. No. 332, at 1 (Aug. 8, 2010), respondent's counsel began assailing the adequacy of Mutual's FDA-mandated labeling within minutes of introducing himself to the jury:

> [T]he evidence will show you that Sulindac was unreasonably dangerous *and had an inadequate warning, as well.* One of the

> easiest ways to show you this will be to show you that they got a new and better warning about six months after Karen Bartlett took the drug. You will learn that the label—the prescription drug label that went along with Sulindac before Karen Bartlett took the drug—[had] a reference to SJS and TEN in ... the adverse reactions section of the label.
>
> You will learn that about six months after Karen Bartlett took this drug Mutual was ordered to put SJS and TEN in the warning section of the label for the first time ever. The label got better. They won't like that word better, but that's exactly what the evidence will show you is what happened.
>
> ***
>
> *You will hear much more evidence about why this label was inadequate in relation to this case.*

CAA1299-1301 (Trial Tr., Aug. 17, 2010, at 110-112) (emphases added).

Once witnesses took the stand, respondent's counsel continued to attack the adequacy of Mutual's FDA-mandated labeling:

> Mr. Jensen: [H]ave you assessed whether [petitioner's] label ... has an effective or adequate warning for SJS/TEN?
>
> Dr. Tackett: I do not think it does have an adequate warning or effective warning.

SPA6a-7a.

> Mr. Jensen: The fact that [FDA later requested a labeling change], what if any bearing does that have on your opinion about the effectiveness or lack thereof of the prior Sulindac label?
>
> Dr. Tackett: Well, it definitely indicates the label was inadequate.

SPA9a.

> Mr. Jensen: What, if any, opinion have you reached as to whether or not [petitioner's] label had an effective warning for SJS and TEN?
>
> Dr. Tackett: As I've said before, I do not think it was effective. The new label basically has a better warning.

SPA12a.

Consistent with respondent's trial strategy, the district court ultimately instructed the jury that it could impose liability *only* if it found that Mutual's FDA-mandated warnings were inadequate:

> If you determine that Sulindac was unreasonably dangerous *and that a warning was not present and effective to avoid that unreasonable danger*, then you must find [respondent] has proven this element of her claim, a defect in design. However, if you determine that Sulindac was unreasonably dangerous, *but that a warning was present and effective to avoid that unreasonable danger*, then you must find for [petitioner].

SPA3a (emphases added).

The jury eventually awarded respondent over $21 million in damages, PA5a, and the district court denied petitioner's post-trial motions (including its renewed preemption arguments). PA69a-76a.

5. Appellate Proceedings

Mutual timely appealed, and the First Circuit affirmed on May 2, 2012. PA1a-26a. The appellate court began its preemption analysis by asserting that this Court "has yet to decide ... [w]hether and to what extent the FDCA preempts design defect claims against generic drug manufacturers." PA8a. To answer that question, it turned to *Wyeth v. Levine*, 555 U.S. 555 (2009)—which, in contrast to *Mensing*, did not involve generic drugs at all. PA8a-9a. Even so, the appellate court asserted that *Wyeth* established a blanket rule "that state law serves as a 'complementary form of drug regulation.'" PA9a (quoting *Wyeth*, 555 U.S. at 578).

In contrast to *Wyeth*'s "general no-preemption rule," PA11a, the First Circuit claimed *Mensing* merely "carved out an exception to *Wyeth*, finding that the FDCA preempts *failure-to-warn* claims against *generic* drug manufacturers [because] the generic maker cannot alter the labeling." PA9a-10a (emphases in original). The court made no effort to explain how design-defect claims are distinguishable from the failure-to-warn claims *Mensing* rejected. Instead, it acknowledged (like the district court) that comment k conditions liability on the inadequacy of drug warnings. PA7a. And it admitted that *Mensing*'s sameness rationale in any event applies equally to labeling- and design-based claims: Just as federal law precludes manufacturers from altering

generic labeling, "Mutual cannot legally make sulindac in another composition." PA10a.

The court nonetheless theorized that the conflict between state-law design requirements and the federal sameness mandate would evaporate if generic manufacturers like Mutual simply refrained from engaging in the federally regulated conduct: "[Mutual] can choose not to make the drug at all; and the FDCA might permit states to tell Mutual it ought not be doing so if risk-benefit analysis weighs against the drug." *Id.* Yet it once again conceded that the stop-selling rationale cannot be squared with *Mensing*, where the same arguments had been made by the Eighth Circuit but not adopted by this Court. PA10a-11a (suggesting this Court might adopt the stop-selling theory "despite what [it] made of similar arguments in the labeling context").

The First Circuit ultimately punted the issue to this Court: "[I]t is up to the Supreme Court to decide whether *[Mensing]*'s exception is to be enlarged to include design defect claims." PA11a.

SUMMARY OF ARGUMENT

Mensing's sameness rationale applies equally to design-defect and failure-to-warn claims, and federal law thus equally preempts both sets of claims. That is so because Hatch-Waxman requires that *both* generic drug labeling *and* generic drug design be materially identical to the design and labeling FDA previously approved for the generic drug's branded equivalent. It therefore is impossible for a generic drug manufacturer to comply both with a state-law requirement that a generic drug's design be safer than the branded equivalent and with the federal requirement that the generic drug's design be

identical to its branded equivalent. State law design-defect claims, just like state law failure-to-warn claims, therefore are preempted by direct operation of the Supremacy Clause.

The stop-selling theory does not reconcile these conflicting state and federal design standards. It only confirms that it is impossible to comply simultaneously with the conflicting standards, and impermissibly ensures that state law prevails—by conditioning the manufacturer's right to engage in interstate commerce on conduct that would violate federal law, and by punishing manufacturers precisely because they complied with federal law. Indeed, if the stop-selling theory is right, there can never be direct conflict preemption; any conflict preemption defense would be foreclosed by the facile assertion that the manufacturer should have withdrawn from the regulated conduct altogether. This Court repeatedly has refused to adopt that radical approach to the Supremacy Clause, and there is no basis for reaching a different result here.

Even if the stop-selling theory somehow evades direct conflict preemption, its application here thoroughly undermines Hatch-Waxman's purposes and objectives. This Court long has recognized that Congress intended Hatch-Waxman's sameness requirement to promote the interstate commercial sale of generic drugs that share a previously approved drug's design, and that textually manifest intent is reflected throughout the statute. The stop-selling theory, by contrast, declares that generic drugs should be removed from the market despite Congress's clear intent to promote their sale. And, more broadly, the stop-selling theory undercuts both

Congress's delegation of vast authority to FDA to control the approval and withdrawal of drugs from interstate commerce *and* the specific statutory protections Congress granted parties aggrieved by the exercise of such authority.

ARGUMENT

I. Respondent's State Law Design-Defect Claim Directly Conflicts With The FDCA's Sameness Requirement.

Since *Mensing*, nearly every other court has rejected the First Circuit's stop-selling rationale for upholding the jury's design-defect verdict—including three federal appellate courts and scores of state and federal trial courts. *See, e.g.*, *Demahy v. Schwarz Pharma, Inc.* [*Demahy III*], __ F.3d __, Nc. 11-31073, 2012 WL 6698692, at *6 (5th Cir. Oct. 25, 2012) (holding that federal law preempts design-defect claims despite plaintiff's post-*Mensing* stop-selling arguments); *Mensing v. Wyeth* [*Mensing II*], 658 F.3d 867 (8th Cir. 2011) (vacating portion of pre-remand opinion embracing stop-selling theory despite plaintiff's post-*Mensing* assertion that the theory survived); *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011) (finding preemption despite plaintiffs' post-*Mensing* stop-selling arguments); *see also* Pet. at 19, 25-27 (collecting cases).

As this widespread consensus underscores, there is no principled basis for reaching a different result here than in *Mensing*. Respondent's state law design-defect claim conflicts just as directly with Hatch-Waxman's federal sameness mandate as the claims everyone agrees *Mensing* held preempted, because the federal sameness mandate applies equally to generic drug design and generic drug

labeling. Nor does the stop-selling rationale reconcile these conflicting state and federal design requirements; it only underscores that it was impossible for Mutual to comply simultaneously with Hatch-Waxman's federal design requirement (to be the same as branded Clinoril®) and the state design requirement embodied in respondent's tort claim (to be different than branded Clinoril®).

A. *Mensing*'s Sameness Rationale Applies Equally To Design-Defect And Failure-To-Warn Claims.

The First Circuit recognized that *Mensing* rejected state tort claims challenging the adequacy of generic drug warnings on the ground that Hatch-Waxman's sameness requirement precludes generic manufacturers from altering their warnings. PA9a-10a ("In [*Mensing*], the Court [held] that [g]eneric manufacturers, unlike brand manufacturers, cannot unilaterally change their labels and thus cannot comply with both federal labeling standards and state law requirements deviating from those standards.") (citations omitted); *see also Mensing*, 131 S. Ct. at 2577 ("Federal [law] prevented the Manufacturers from independently changing their generic drugs' safety labels.... It [therefore] was not lawful under federal law for the Manufacturers to do what state law required of them."); *id.* at 2581 ("Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action.... [Plaintiffs'] tort claims are pre-empted.").

The appellate court nonetheless thought it could evade *Mensing*'s holding by repeatedly asserting that the decision addressed only failure-to-warn claims—

not design-defect claims. PA9a ("[*Mensing* held only] that the FDCA preempts failure-to-warn claims.") (emphasis original); PA10a ("[T]he Supreme Court [has] not yet said it would extend [*Mensing*] to design defect claims."); PA11a ("[I]t is up to the Supreme Court to decide whether [*Mensing*] is to be enlarged to include design defect claims.").

That was error. Both the *Mensing* and *Demahy* complaints asserted failure-to-warn *and* design-defect claims (*supra* at 14), and those cases arrived here only after the lower courts found there was no basis for distinguishing among the myriad claims because each ultimately turned on the generic drug's FDA-mandated warnings. *Demahy III*, 2012 WL 6698692, at *6 ("Demahy's only remaining claims [were] characterized by the district court, this Court, and the Supreme Court as failure-to-warn claims."); *Mensing*, 562 F. Supp. 2d at 1061 n.6 ("[A]ll of Plaintiff's claims are essentially 'failure to warn' claims and are encompassed by the Court's preemption analysis."). That explains why *Mensing* held that "federal law pre-empts *these lawsuits*," not merely the claims plaintiffs had captioned "failure-to-warn." 131 S. Ct. at 2581 (emphasis added).

Even if it *Mensing* had been limited to failure-to-warn claims, the First Circuit provided no rationale for distinguishing between failure-to-warn and design-defect claims for preemption purposes—and there is none, as the First Circuit seemed to recognize. PA11a ("To refuse preemption here is ... in tension ... with ... [*Mensing*]'s rationale."). That is so because Hatch-Waxman demands not only that generic *labeling* be "'the same as the labeling approved for the [brand-name] drug,'" *Mensing*, 131

S. Ct. at 2574 (quoting 21 U.S.C. § 355(j)(2)(A)(v) (alteration in original)), but also that generic *design* be the same. It thus requires each generic drug to contain "*the same*" active ingredient(s); employ "*the same*" route of administration; present "*the same*" dosage form; and exhibit "*the same*" strength as its branded equivalent, so that it will "have *the same* therapeutic effect" and safety profile as the branded equivalent. 21 U.S.C. § 355(j)(2)(A)(i)-(iv) (emphases added); *see also Mensing*, 131 S. Ct. at 2574 n.2 (explaining that generic drugs must be "identical in active ingredients, safety, and efficacy"). Indeed, Hatch-Waxman requires that generic labeling be materially identical to branded labeling *precisely because* generic design must be materially identical to branded design. *Final ANDA Rule*, 57 Fed. Reg. at 17961 ("[T]he ANDA product's labeling must be the same as the [branded] product's labeling *because* the [branded] drug product is the basis for ANDA approval.") (emphasis added).

Federal law thus gives manufacturers no more power to alter generic drug design than it does to alter generic drug labeling. Given the sameness mandate, generic manufacturers would violate federal law if they unilaterally altered *either* their FDA-mandated labeling *or* their FDA-mandated design; the resulting product could not lawfully be sold in interstate commerce. 21 U.S.C. § 355(a). Indeed, without the same active ingredient—sulindac, which is the design component to which respondent attributed her injuries—the resulting drug no longer would be a generic copy of a branded drug at all; it would be a different drug entirely.

Mensing's sameness rationale for rejecting claims challenging generic drug *labeling* thus applies with equal force to claims challenging generic drug *design*, because generic manufacturers "cannot comply with both a state law duty to make a safer design and the federal requirement that the generic drug design be the equivalent of the brand name drug." *Frazier v. Mylan Inc.*, __ F. Supp. 2d __, 2012 WL 6641626, at *6 (N.D. Ga. Dec. 18, 2012); *see also Aucoin v. Amneal Pharm.*, LLC, No. 11-1275, 2012 WL 2990697, at *9 (E.D. La. July 20, 2012) ("Defendant could not alter the design of the drug without violating federal law and this duty of sameness, making it impossible for Defendant independently to comply with both federal and state law."); *Johnson v. Teva Pharms. USA, Inc.*, 2012 WL 1866839, at *4 (W.D. La. May 21, 2012) ("The FDCA likewise prevented the Generic Defendants from altering unilaterally the design of the drug itself."); *Eckhardt v. Qualitest Pharm. Inc.*, 858 F. Supp. 2d 792, 801 (S.D. Tex. 2012) ("Generics were required to produce a drug that was equivalent to the brand-name drug and were not free to unilaterally pursue a safer alternative design."); *In re Darvocet*, No. 11-2226, 2012 WL 718618, at *3 (E.D. Ky. Mar. 5, 2012) ("[Plaintiffs] have not demonstrated that their so-called wrongful marketing claims escape preemption. The claims ... are all based on the allegedly defective design of the drug, which the Generic Defendants, bound by their ongoing federal duty of sameness, were powerless to change.") (quotation omitted); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012) ("[T]he federal duty of sameness also applies in the context of generic drug design, and federal law preempts state laws imposing a duty

to change a drug's design.") (citation and quotation omitted); *Stevens v. PLIVA, Inc.*, No. 10-0886, 2011 WL 6224569, at *2 (W.D. La. Nov. 15, 2011) ("Under the same federal law analyzed in *Mensing*, a generic pharmaceutical product must be the same as [its branded equivalent] in active ingredients, safety and efficacy and hence, as was the case with labeling, federal law pre-empts state laws imposing the duty to change a drug's design.") (citation omitted).

Indeed, design-defect claims are preempted not only under *Mensing*'s sameness *rationale*; they are preempted even under the narrow *holding* that the First Circuit attributed to *Mensing*—*i.e.*, that "the FDCA preempts failure-to-warn claims against generic drug manufacturers." PA9a. After all, this Court recognized just last year that failure-to-warn claims are in fact design-defect claims. *Kurns v. Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1268 (2012) ("A failure-to-warn claim alleges that a product is defective."); *id.* at 1268 n.4 ("A failure-to-warn claim imposes liability on a particular design ... and the accompanying threat of liability will inevitably influence a manufacturer's choice whether to use that particular design."). That recognition forecloses the First Circuit's attempt to draw a bright line between failure-to-warn and design-defect claims for preemption purposes; it underscores that *Mensing* in fact encompassed design-defect claims, whether they were labeled as such or not.

Perhaps more important, the flipside of *Kurns*'s insight regarding the nature of failure-to-warn claims is equally true: At least in the prescription-drug context, *design-defect claims are failure-to-warn claims*. That is so because New Hampshire (like the

overwhelming majority of states, *see* Addendum B) follows comment k to *Restatement (Second) of Torts* § 402A—as the First Circuit recognized, PA7a, and respondent unequivocally has conceded here. BIO 3-4. Because such products are "unavoidably unsafe," comment k renders them "exempt from strict liability" so long as they are "'properly prepared, and accompanied by proper directions and warning.'" BIO 4 (quoting comment k). Accordingly, whatever distinctions there may be between design-defect and failure-to-warn claims outside this context, those claims collapse together in cases targeting drugs.[7]

As Mutual thus explained below, respondent's design-defect claim never should have gone to trial because it necessarily and impermissibly hinged on challenging the adequacy of Mutual's FDA-mandated warnings. Preemption MSJ, 2010 WL 1371985, at 31-32 ("[D]rugs are unavoidably unsafe products, and as such, cannot be defective in design as long as they are accompanied by adequate warnings. As such, any design claim directly implicates warnings and thus, falls under the same preemption analysis.").[8]

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[7] Indeed, even outside the comment k context, New Hampshire law requires consideration of the adequacy of a product's warnings as part of its standard design-defect analysis. *Price v. BIC Corp.*, 142 N.H. 386, 389 (N.H. 1997) ("[W]hether a product's design is unreasonably dangerous [requires] evaluation of many conflicting factors [including] the presence and efficacy of a warning to avoid an unreasonable risk of harm.") (quotation omitted).

[8] The appellate court seemed to fault Mutual for withdrawing its comment k defense for trial purposes and thereby refusing to defend the adequacy of its FDA-mandated warnings in court. PA7a-8a & n.1. That is entirely backwards: Mutual's whole

Indeed, the district court's eventual jury instructions sharply underscored this fatal defect in respondent's design-defect claim:

> If you determine that Sulindac was unreasonably dangerous *and that a warning was not present and effective to avoid that unreasonable danger*, then you must find [respondent] has proven this element of her claim, a defect in design. However, if you determine that Sulindac was unreasonably dangerous, *but that a warning was present and effective to avoid that unreasonable danger*, then you must find for [petitioner].

SPA3a (emphases added).

Accordingly, the First Circuit did not err merely because *Mensing*'s sameness rationale applies equally to both design-defect and failure-to-warn claims. It erred because the jury's verdict ultimately hinged as a matter of state law on the one thing everyone agrees *Mensing* held it could not: a decision that Mutual's FDA-mandated labeling was inadequate. *Mensing* thus squarely forecloses the sole claim on which the jury based its verdict.

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point is (and always was) that Hatch-Waxman's sameness requirement placed Mutual's FDA-mandated labeling beyond the jury's purview, since (as *Mensing* later held) the sameness requirement precluded Mutual from altering those warnings. It would defy *Mensing* to suggest that Mutual somehow was obligated to prove as a factual matter at trial what Hatch-Waxman establishes as a matter of federal law.

B. Respondent's Stop-Selling Theory Only Exacerbates The Conflict Between State And Federal Law.

The First Circuit acknowledged that Hatch-Waxman's sameness mandate grants generic manufacturers no more power to alter the design of their drugs than it does to alter the labeling of their drugs. PA10a ("Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)."). And it recognized that design-defect liability in New Hampshire turns on the adequacy of a product's warnings. PA7a ("[A]n ordinary consumer would hardly know without further warning that sulindac ... carries a risk of the kind of ill effects and suffering that Bartlett encountered.").

The court nonetheless asserted that finding preemption here would conflict with *Wyeth*'s alleged adoption of "a general no-preemption rule," PA11a, and held that any conflict between Hatch-Waxman's sameness mandate and respondent's state-law claim could be avoided if Mutual simply pulled its products off the market. PA10a ("[Mutual] certainly can choose not to make the drug."); PA10a-11a ("[T]he decision to make [sulindac] and market it in New Hampshire is wholly [Mutual's]."). Neither assertion resolves the direct conflict between the federal and state generic drug design requirements at issue here.

The First Circuit's reliance on *Wyeth* is simply bizarre. Unlike *Mensing*, *Wyeth* concededly did not involve generic drugs *or* design-defect claims. PA9a & n.2 ("*Wyeth*'s holding was technically limited to failure-to-warn claims.... More specifically, *Wyeth* held that the FDCA does not preempt failure-to-warn

claims against brand-name drug manufacturers.") (citing *Wyeth*, 555 U.S. at 568, 573). Nor did *Wyeth* "adopt[] a general no-preemption rule." PA11a. It merely held that a state-law claim challenging Wyeth's warnings could proceed because federal law specifically authorized Wyeth to change those warnings unilaterally. *Wyeth*, 555 U.S. at 571 ("[W]hen the risk of gangrene from IV-push injection of Phenergan became apparent, Wyeth had a duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval."). As *Mensing* recognized, *Wyeth* thus stands for the unremarkable proposition that state law can hold the manufacturer of a federally regulated product liable where federal law expressly empowers that manufacturer to alter its product to comply with the substantive duty embodied in the plaintiff's tort claim. *Mensing*, 131 S. Ct. at 2581 ("[T]he federal regulations applicable to Wyeth allowed the company, of its own volition, to strengthen its label in compliance with its state tort duty ... to provide an adequate warning label.").

That proposition has no applicability here, because it is beyond dispute that federal law gave Mutual no such power. As the appellate court recognized, the federal sameness requirement barred Mutual from altering sulindac's design to comply with New Hampshire's demand that its drug be safer than brand-name Clinoril®, PA10a, just as the federal sameness requirement barred the *Mensing* defendants (but not the *Wyeth* defendant) from altering their drug labels to comply with state tort-law demands to more "safely label their products"

than those products' branded equivalents. *Mensing*, 131 S. Ct. at 2577.

Faced with that reality, the First Circuit ultimately asserted that it remained possible for Mutual both to design its product to comply with Hatch-Waxman's federal sameness requirement and then choose not to sell that product if it wanted to avoid state tort liability. PA10a-11a. It therefore held respondent's design-defect claim survived Mutual's preemption defense, "despite what the Supreme Court made of similar arguments" advanced in the Eighth Circuit's pre-*Mensing* opinion. PA10a; *see also Mensing I*, 588 F.3d at 611 ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient ... they could have simply stopped selling the product.").

The First Circuit offered no reason why the result should be any different here than in *Mensing*, which of course reversed the Eighth Circuit's decision. It simply asserted that this Court might reach the opposite result out of sympathy for respondent. PA11a ("Bartlett having lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief."[9]). But this Court left no doubt that Congress's "special, and different, regulation of generic drugs" required

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[9] The court's assertion that respondent "lost her warning claim" because of *Mensing* misses the mark. Respondent never had a "warning claim" against Mutual because her physician never read Mutual's warnings. PA117a.

preemption, even as it "acknowledge[d] the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, *and others similarly situated*." 131 S. Ct. at 2581-82 (emphasis added). The same federal law addressed in *Mensing*—Hatch-Waxman's sameness mandate—applies no less to claims targeting generic drug design than claims targeting generic drug labeling, and the admittedly tragic facts of this case are not grounds for jettisoning *Mensing*'s straightforward application of the Supremacy Clause.

Indeed, this Court made clear even before *Mensing* that the appellate court's radical theory of liability does not resolve the direct conflict between state and federal law; rather, it perversely ensures that state law reigns supreme, by conditioning the right to engage in interstate commerce free from state-law liability on conduct that would violate federal law. The Supremacy Clause forbids that approach. This Court long ago held that state law "is pre-empted by direct operation of the Supremacy Clause" where it prevents "the exercise of ... federally protected rights." *Brown v. Hotel & Rest. Employees & Bartenders Int'l Union Local 54*, 468 U.S. 491, 501 (1984). And it likewise has recognized that state tort law directly and thus impermissibly conflicts with federal law even though it remains possible for the manufacturer of a federally regulated product to both comply with federal law and pay damages to state tort plaintiffs who later demonstrate that the manufacturer's compliance with federal standards violated state law. *See, e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992) (plurality) & *id.* at 548-49 (Scalia, J.,

concurring in relevant part); *see also MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1025 (5th Cir. 1994); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370 (7th Cir. 1993); *Palmer v. Liggett Group, Inc.*, 825 F.2d 620, 627 (1st Cir. 1987).

That is so because "common-law liability is 'premised on the existence of a legal duty,' and a tort judgment therefore establishes that the defendant has violated a state-law obligation." *Riegel*, 552 U.S. at 324 (quoting *Cipollone*, 505 U.S. at 522); *Cipollone*, 505 U.S. at 521 ("As we noted in another context, 'state regulation can be as effectively exerted through an award of damages as through some form of preventive relief.'") (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)); *cf. Plains Commerce Bank v. Long Family Land & Cattle Co.*, 554 U.S. 316, 331-32 (2008) ("[T]ribal tort law ... regulates the substantive terms on which the Bank is able to offer its fee land for sale [and] is a form of regulation.") (citing *Riegel*, 552 U.S. at 324).

It thus is irrelevant that "the common-law remedy is limited to damages," which of course can be paid by unsuccessful tort defendants (just as defendants can avoid even the possibility of damages liability by pulling their products from interstate commerce). *Riegel*, 552 U.S. at 324. Whether or not a defendant is capable of writing a check because it "chose" to comply with controlling federal standards instead of contrary state requirements, the fact remains that those federal standards directly conflict with "the legal duty that is the predicate of the common-law damages action." *See, e.g.*, *Cipollone*, 505 U.S. at 524; *Riegel*, 524 U.S. at 324 ("[A] liability award can be, indeed is designed to be, a potent

method of governing conduct.") (quotations omitted); *see also Wyeth*, 555 U.S. at 590 (Thomas, J., concurring) ("[I]f federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior.") (citing Caleb Nelson, *Preemption*, 86 VA. L. REV. 260-61 (2000)).

If the Supremacy Clause preempts state-law *damage awards* predicated on a standard that conflicts with federal law, it surely preempts states from enforcing the same conflicting standard by *banning the sale of a federally compliant product altogether*. The same principle applies in both cases, and is perfectly illustrated here. Even if Mutual's FDA-mandated warnings played no role in this case—and they assuredly did—the legal duty giving rise to respondent's design-defect claim under New Hampshire law directly conflicts with Hatch-Waxman's federal sameness mandate. Under New Hampshire law, Mutual's basic duty was to "design [its drug] reasonably safely for the uses [Mutual] can foresee." *Thibault v. Sears, Roebuck & Co.*, 118 N.H. 802, 809 (1978). The jury's verdict "therefore establishes that [Mutual] violated a state-law obligation" to design its drug to be "reasonably safe" under the jury's *ad hoc* interpretation of that standard. *Riegel*, 552 U.S. at 324.

The problem, of course, is that Hatch-Waxman establishes a different design standard: It required Mutual's sulindac design to be "the same" as brand-name Clinoril®, 21 U.S.C. § 355(j)(2)(A), in order to guarantee that Mutual's generic drug would be

"identical" to brand-name Clinoril® in terms of both "safety, and efficacy." *Mensing*, 131 S. Ct. at 2574 n.2. Federal law thus forbade Mutual from satisfying its state-law obligation to design a product with a different safety profile than the one FDA approved (and continues to approve). PA10a ("Mutual cannot legally make sulindac in another composition."). If the Supremacy Clause means anything, it means that state law cannot condition the right to engage in interstate commerce on conduct that would violate federal law or punish parties for complying with controlling federal standards from which they cannot lawfully deviate; the substantive duty embodied in respondent's design-defect claim unquestionably is a "Thing in the Constitution or Laws of any State to the Contrary," and therefore must yield to federal law. U.S. CONST. art VI, cl. 2.

The First Circuit's facile assertion that Mutual could have "cho[sen] not to make the drug at all," PA10a, thus does nothing to *reconcile* the direct conflict between the state and federal design standards. It only highlights that it was *impossible* for Mutual to comply simultaneously with Hatch-Waxman's federal design requirements and the jury's *ad hoc* interpretation of New Hampshire's apparently contrary design requirements. That is what impossibility *means*: that a person cannot comply simultaneously with both state and federal standards, and thus must cease acting at all.

Accepting the First Circuit's stop-selling rationale thus would foreclose ordinary conflict preemption of state tort claims involving *any* federally regulated product. Because *every* manufacturer can in theory

"choose" to stop making a given product, no federal requirement could ever generate a direct preemptive conflict. *See In re Darvocet*, 2012 WL 718618, at *3 ("[T]he idea that [the generic defendants] should have simply stopped selling propoxyphene is an oversimplified solution that could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether.").

Indeed, the appellate court's radical theory of liability would produce an array of absurd results. If, for instance, the State of California required pharmacists to dispense medical marijuana as a condition of doing business in the state—and thereby violate the federal Controlled Substances Act—no serious person would suggest the California law survives the pharmacist's preemption defense simply because federal law does not compel anyone to be a pharmacist. Yet that is precisely what the First Circuit held in this case: Because the pharmacist in theory can "comply" with both state and federal law by "choosing" not to be a pharmacist at all, she would have no defense.

Or suppose state law allows the governor to fire employees who do not contribute to her reelection campaign. The First Amendment conflicts with that law, and under the Supremacy Clause thus trumps the state law. It used to be said there was no conflict because the employee could cease working for the state (and indeed had no right to do so in the first place). *See McAuliffe v. Mayor of New Bedford*, 155 Mass. 216, 220 (1892) (Holmes, J.) ("[P]etitioner may have a constitutional right to talk politics, but he has

no constitutional right to be a policeman."). That view, of course, has been repudiated for decades. *See, e.g.*, *O'Hare Truck Serv., Inc. v. City of Northlake*, 518 U.S. 712, 716-17 (1996). Yet the First Circuit's "stop-selling" theory is logically indistinguishable from the "stop-working" theory. The option of withdrawing from the field does not eliminate the conflict between the state requirement and federal authorization. It is just a way to ensure state law prevails over federal law.

That *cannot* be correct—and *Mensing* made clear it *is* not correct, by declaring that this Court could "not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless. The Supremacy Clause, on its face, makes federal law 'the supreme Law of the Land' even absent an express statement by Congress." 131 S. Ct. at 2579 (quoting U.S. CONST. art. VI, cl. 2). That commonsense holding controls here, and the decision should be reversed.

II. Respondent's State Law Design-Defect Claim Eviscerates The FDCA's Purposes and Objectives.

Even if it did not directly conflict with Hatch-Waxman's sameness requirement—and it does—respondent's state law design-defect claim still would be preempted. For more than 70 years, this Court has made clear that the Supremacy Clause preempts any state law (including any tort claim) that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" even absent a direct conflict with federal law. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *see also Williamson v. Mazda Motor of Am., Inc.*, 131 S. Ct.

1131, 1136 (2011); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 881-82 (2000); *International Paper Co. v. Ouellette*, 479 U.S. 481, 493 (1987); *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 156 (1982); *Perez v. Campbell*, 402 U.S. 637, 649-50 (1971). Respondent expressly concedes the legitimacy of this well-settled rule. BIO 27-28 ("Federal law continues to preempt state tort suits that frustrate the accomplishment of Congress's purposes and objectives, regardless of whether the defendant could comply with state law by suspending sales of its product.").[10]

If ever there were a case for purposes-and-objectives preemption, this is it. The stop-selling end-run around Hatch-Waxman's federal sameness requirement self-consciously undermines Congress's manifest intent to ensure the sale of generic copies of FDA-approved drug designs, by ordering those products off the market precisely because they replicate FDA-approved designs.

A. The Stop-Selling Theory Thwarts Hatch-Waxman's Central Objective Of Ensuring That Generic Drugs Are Available For Sale In Interstate Commerce.

This Court repeatedly has explained that Hatch-Waxman's central objective is to ensure that generic copies of previously approved drugs are available for sale in interstate commerce whenever their costly brand-name equivalents come off patent. *See, e.g.*,

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[10] Given the parties' unqualified agreement that *Hines* supplies the proper constitutional test, there is no reason to question its legitimacy here.

Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012) ("Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug. *As we have previously recognized, this process is designed to speed the introduction of low-cost generic drugs to market.*") (citation omitted; emphasis added; referencing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) ("[T]o enable new drugs to be marketed more cheaply and quickly, [Hatch-Waxman] substantially shorten[ed] the time and effort needed to obtain [generic] marketing approval.") (citation omitted)); *Mensing*, 131 S. Ct. at 2582 ("[I]t is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public.").

And unlike other cases—where assessing Congress's intent arguably depends "on extratextual judicial suppositions," or requires courts to "wade[] into a sea of agency musings and Government litigating positions," *Williamson*, 131 S. Ct. at 1142 (Thomas, J., concurring)—this Court's longstanding assessment of Hatch-Waxman's core objectives stems directly from "federal standards and policies that are set forth in, or necessarily follow from, the statutory text that was produced through the constitutionally required bicameral and presentment procedures." *Wyeth*, 555 U.S. at 586 (Thomas, J., concurring). Indeed, nearly every subsection of Hatch-Waxman's generic-drug provisions reflects Congress's textually manifest goal of ensuring that such drugs are available to compete for sales in the interstate

marketplace, beginning with the title Congress selected: "the *Drug Price Competition* and Patent Term Restoration Act of 1984." Hatch-Waxman Act, 98 Stat. at 1585 (emphasis added); *see also INS v. National Ctr. for Immigrants' Rights, Inc.*, 502 U.S. 183, 189 (1991) ("[T]he title of a statute or section can aid in resolving an ambiguity."); *United States v. Fisher*, 6 U.S. (2 Cranch) 358, 386 (1805) (Marshall, C.J.) ("[T]he title claims a degree of notice, and will have its due share of consideration.").

To that end, Hatch-Waxman's substantive provisions seek to both facilitate and encourage the sale of generic drugs that share previously approved designs. The statute begins by creating an "abbreviated" pathway that expressly requires FDA to approve bioequivalent generic drugs that use "*the same*" active ingredient(s), routes of administration, dosage forms, and strengths as previously approved brand-name drugs. Hatch-Waxman Act, § 101, 98 Stat. at 1585-86 (emphasis added; codified at 21 U.S.C. § 355(j)(1)-(2)(A)); *id.*, 98 Stat. at 1587 ("[FDA] shall approve an [ANDA] unless [the sameness criteria are not met].") (codified at 21 U.S.C. § 355(j)(4)). Again, this Court long has recognized that these provisions evince Congress's intent to make generic copies of previously approved drug designs available for sale whenever branded patents expire. *See, e.g., Caraco*, 132 S. Ct. at 1676; *Mensing*, 131 S. Ct. at 2582; *Eli Lilly*, 496 U.S. at 676.

To ensure prompt FDA action on generic *applications* and thereby expedite the entry of generic *products* into interstate commerce, Hatch-Waxman next provides that the Agency "may not require that an abbreviated application contain

information in addition to that required by [the sameness] clauses." Hatch-Waxman Act, § 101, 98 Stat. at 1586 (codified at 21 U.S.C. § 355(j)(2)(A)). And it directs FDA to either approve or disapprove each submitted ANDA "[w]ithin [180] days" unless the applicant agrees otherwise. *Id.*, 98 Stat. at 1588 (codified at 21 U.S.C. § 355(j)(4)(A)).

Finally, to ensure generic manufacturers take full advantage of the abbreviated pathway, Hatch-Waxman creates a lucrative incentive for generic applicants to both challenge competition-blocking patents and submit ANDAs at the earliest chance: It rewards the first generic applicant that submits an ANDA that challenges a patent which covers the referenced name-brand drug with a 180-day exclusivity period during which no other ANDA for that drug can be approved. *Id.*, 98 Stat. at 1589 (codified as amended at 21 U.S.C. § 355(j)(5)(B)(iv)).

As with Hatch-Waxman's sameness provisions, the courts repeatedly have recognized that Congress intended the 180-day exclusivity provision to drive marketplace competition by ensuring not only that generic products *can* enter interstate commerce, but that they *actually do so*—both early and often. *See, e.g., Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) ("This promise of initial marketing exclusivity is thus intended to increase competition by expediting the availability of generic equivalents."); *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) ("The legislative purpose underlying [180-day exclusivity] is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA holders in order to bring generic

drugs to market earlier."); *see also Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008); *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006).

Suffice it to say, the stop-selling theory cannot be squared with the legislative objectives manifested by these specific statutory provisions—each of which is calibrated not only to *allow* interstate commercial sale of generic drugs that share a previously approved design, but to *ensure* that such drugs enter interstate commerce as often and early as possible. Accepting the appellate court's stop-selling theory of liability thus "would take [away] the very ability to achieve the law's congressionally mandated objectives that the Constitution, through the operation of ordinary pre-emption principles, seeks to protect." *Geier*, 529 U.S. at 872.

The legislative history accompanying Hatch-Waxman confirms what the statutory text makes clear: Congress intended to ensure that generic copies of previously approved drug designs are available for sale in interstate commerce whenever their branded equivalents come off patent. As the House Report explained, "[t]he purpose of Title I of the bill is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962.... The availability of generic versions of pioneer drugs approved after 1962 would save Americans $920 million over the next 12 years." H. Rep. 98-857 pt. 1, at 14-17 (1984).

Key players in the debate repeatedly echoed that view. Representative Waxman explained:

> [This bill] is the most important drug legislation to come before the Congress since the 1962 [Act]. It is also the most important consumer legislation to be considered this Congress. The bill will save consumers over $1 billion by making more low cost generic drugs available.
>
> ***
>
> Unfortunately, the[] abbreviated generic drug approval procedures [for certain pre-1962 drugs] do not apply to pioneer drugs approved after 1962. The lack of such procedures is an effective bar to generic competition because the generic companies cannot afford the millions of dollars to duplicate the test results already in the FDA's files.
>
> ***
>
> By making these drugs available as generics, H.R. 3605 will reduce the cost of drugs for all consumers.

130 Cong. Rec. H8706 (Aug. 8, 1984) (statement of Rep. Waxman).

The legislative history also underscores that Congress deliberately required generic drug design to be materially identical to branded drug design because FDA already approved that design—which is the only way Congress could both eliminate the clinical study requirement *and* ensure that patient safety would not be compromised by generic drugs. *See, e.g.*, 130 Cong. Rec. H8703 (Aug. 8, 1984) (statement of Rep. Derrick) ("[P]harmaceutical companies which produce generic drugs must

undertake a lengthy and expensive procedure in order to gain FDA approval for sale of a drug ... *despite the fact that ... FDA has previously approved the sale of the exact same drug by the company holding the patent. This bill seeks to end this duplication of effort and, more importantly, make it easier for pharmaceutical companies to market cheaper, generic alternatives.*") (emphasis added); 130 Cong. Rec. H9144 (Sept. 6, 1984) (statement of Rep. Walgren) ("[This legislation] will make hundreds of new low-cost, generic drugs available by speeding up the approval process for these drugs. As the current law stands, [post-1962 drugs] can only be made available in generic form through a long and involved testing process. *This process is unnecessary because the active ingredient in the generic drug is identical to that in the name-brand drug. Under H.R. 3605, this testing process would be speeded up tremendously without endangering the safety to the consumer.*") (emphasis added).

There is thus no question that the stop-selling theory thwarts Congress's goal of ensuring that generic copies of previously approved drug designs are available to compete for sales in interstate commerce. Whereas federal law authorizes and encourages the sale of such products in interstate commerce, the stop-selling theory by design seeks to punish companies like Mutual for doing just that. This Court repeatedly has rejected far less dramatic state efforts to undermine federal objectives. *See, e.g., Kurns*, 132 S. Ct. at 1269 (rejecting as "contrary to common sense" arguments that federal law preempts state-law claims targeting railroad operators but not locomotive manufacturers because "a railroad's ability to equip its fleet of locomotives in

compliance with federal standards is meaningless if manufacturers are not allowed to produce locomotives ... that meet those standards"); *Engine Mfrs. Ass'n v. South Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 255 (2004) (explaining it "would make no sense" to treat state "sales restrictions and purchase restrictions differently for pre-emption purposes" because the "right to sell federally approved [products] is meaningless in the absence of a purchaser's right to buy them"). There is no reason to reach a different result here.

B. The Stop-Selling Theory Thwarts The FDCA's Vesting Of Authority Over Interstate Pharmaceutical Marketing In FDA And Undermines The Statutory Protections Congress Granted Drug Manufacturers.

Beyond eviscerating Hatch-Waxman's central objective, the stop-selling theory fatally undermines the broader FDCA scheme. On one hand, it thwarts Congress's decision to vest FDA with authority to determine both when the scientific record is sufficient to permit the sale of drugs in interstate commerce and when that record requires that such products be withdrawn from interstate commerce. On the other hand, it undermines the specific statutory protections Congress gave manufacturers whose right to engage in interstate commerce might be affected by the exercise of that authority.

Indeed, the FDCA's long history evinces a clear intent to both centralize FDA control over the marketing of drugs in interstate commerce *and* to circumscribe the conditions under which FDA may order approved drugs withdrawn from interstate

commerce. To that end, the 1938 Act imposed strict federal approval requirements for drugs intended for interstate commercial sale, 1938 Act, § 505(b), 52 Stat. at 1052, and empowered FDA to suspend interstate sale approval in limited circumstances. *Id.* § 505(e), 52 Stat. at 1053. The 1962 Act went even further: It for the first time empowered FDA to consider drug effectiveness in exercising this authority, 1962 Act, § 102(c), 76 Stat. at 781, and expanded the range of conditions under which FDA could order approved drugs withdrawn from interstate commerce. *Id.* § 102(d), 76 Stat. at 782.

At each turn, Congress augmented the statutory protections for companies whose products were subject to FDA's continually expanding withdrawal authority. The 1938 Act granted manufacturers notice and hearing rights before an approval could be suspended; required FDA to memorialize its rationale for any suspension decision; and granted aggrieved parties the right to record-based judicial review of suspension decisions in federal district court. 1938 Act, §§ 505(e), (h), 52 Stat. at 1053. In 1962, Congress provided additional notice and hearing rights in cases where FDA was considering exercising its expanded withdrawal authority, 1962 Act, § 102(d), 76 Stat. at 782, and it transferred judicial review of withdrawal orders to the federal appellate courts. *Id.* § 104(d)(1), 76 Stat. at 784.

Hatch-Waxman ensured the same protections were available to generic manufacturers. *See* 21 U.S.C. §§ 355(e), (h) (requiring "due notice and opportunity for hearing to the applicant" whenever FDA seeks to "withdraw approval of an application *with respect to any drug under this section*" and

providing direct federal appellate review whenever FDA "withdraw[s] approval of *an application under this section*") (emphases added). Even more recently, Congress's 1997 amendments directed FDA to implement standards for "technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, ... which shall apply equally to all individuals who review such applications." Food and Drug Administration Modernization Act of 1997, § 119(a), Pub. L. No. 105-115, 111 Stat. 2296, 2316 (codified at 21 U.S.C. § 355(b)(5)(A)) (NDAs); *id.* § 119(b), 111 Stat. at 2317-18 (codified at 21 U.S.C. § 355(j)(3)(A)) (ANDAs).

The stop-selling theory cannot be squared with this long history. It undercuts the statute's carefully circumscribed vesting of authority in FDA to control which drug designs can enter and remain in interstate commerce. *See, e.g.*, *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011) ("[A] state law duty that would compel generic manufacturers to stop production of a drug that under federal law they have the authority to produce ... would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce."); *see also Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1352 n.14 (N.D. Ga. 2012) ("[A]ny such state law duty [to withdraw a generic drug from interstate commerce] would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce."); *Aucoin*, 2012 WL 2990697, at *9 (E.D. La. July 20, 2012) ("To require a generic

manufacturer to remove a drug from the market would repudiate ... the FDA.").

Indeed, allowing lay juries to second-guess FDA's decision to maintain interstate marketing approval for certain drug designs strikes at the heart of Congress's decision to vest such authority in FDA. That delegation of authority reflects the principle that such decisions should be made in a systematic, evidence-based manner by an expert federal agency—not laypersons who lack the technical skill and experience of FDA's scientific experts in evaluating pharmaceutical designs. *See, e.g.*, *Riegel*, 552 U.S. at 325 ("[O]ne would think that tort law, applied by juries under a negligence or strict-liability standard, is [even] less deserving of preservation [than a] state statute, or a regulation adopted by a state agency, [which] could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA.... A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."); *see also* Stephen Breyer, *Active Liberty: Interpreting Our Democratic Constitution* 102-03 (2005) ("Without delegation to experts, an inexpert public, possessing the will, would lack the way.").

That deliberate policy choice is clearly reflected in the 1997 amendments' requirement that FDA establish expertise-driven qualifications that "shall apply equally *to all individuals* who review [drug] applications." 21 U.S.C. § 355(b)(5)(A) (NDAs) (emphasis added); *id.* § 355(j)(3)(A)) (ANDAs). Needless to say, it is impossible to apply those congressionally required qualifications to lay jurors

that the stop-selling theory charges with reviewing whether a given drug design should remain approved for interstate commercial sale.

The same policy likewise is reflected in the laundry list of cases where federal courts have refused under *Chevron* to second-guess FDA's expert decisions governing the approval of drugs for sale in interstate commerce. *See, e.g.*, *Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 766 (D.C. Cir. 2010) ("We are hard pressed to second-guess the FDA's view, especially since it rests on the agency's evaluation of scientific data within its area of expertise.") (quotation omitted); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1324 (D.C. Cir. 1998) ("FDA's 'judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us.'") (quoting *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995)); *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) ("FDA possesses the requisite know-how to conduct such [scientific] analyses, by sifting through the scientific evidence to determine the most accurate and up-to-date information regarding a particular drug.... We therefore defer to its reasonable findings."); *see also Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653-54 (1973) ("Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background. The determination whether a drug is ... safe and effective ... necessarily implicates complex chemical and pharmacological considerations.") (quotation omitted).

The stop-selling theory also strips parties of the specific statutory protections federal law grants them before their products lawfully can be ordered withdrawn from interstate commerce. Again, those provisions explicitly require (among other things) the production of a written decision detailing the rationale for ordering FDA-approved drugs withdrawn from interstate commerce, 21 U.S.C. §§ 355(e), (g), and not only vest the federal appellate courts with exclusive jurisdiction and direct review authority over such decisions but declare that "[t]he finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive." *Id.* § 355(h). Without belaboring the point, state-law tort verdicts provide none of the specific protections that Congress repeatedly has extended to parties whose products effectively are being forced off the market.[11]

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[11] It is no answer that a civil trial arguably provides *similar* protections. As this Court repeatedly has explained, the means Congress has chosen are as important as the ends. *See, e.g.*, *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 379 (2000) ("The fact of a common end hardly neutralizes conflicting means.") (citing *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 103 (1992) (plurality opinion) ("'A state law also is pre-empted if it interferes with the methods by which the federal statute was designed to reach th[at] goal.'") (quoting *Ouellette*, 479 U.S. at 494, with alteration)); *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 n.4 (1994) ("[W]e ... are bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes."); *see also Block v. Community Nutrition Inst.*, 467 U.S. 340, 349 (1984) ("[W]hen a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial

C. *Wyeth* Is Not To The Contrary.

To its credit, the First Circuit conceded that the stop-selling theory undermines *both* Hatch-Waxman's core objectives *and* the FDCA's vesting in FDA of authority over the withdrawal of drugs from interstate commerce. PA10a ("There is no doubt that Congress wanted to reduce medical costs by spurring generic copycat drugs [and *Mensing*] held that Congress cannot have wanted the generic to pay damages under state law for a label that the FDA required.") (citing *inter alia* 21 U.S.C. § 355(j)(2)(A)); *id.* (acknowledging that the stop-selling theory requires "second-guessing the FDA"). Nonetheless, the appellate court once again thought it could evade those concessions by asserting that *Wyeth* "adopted a general no-preemption rule." PA11a.

As previously explained, that simply is not so. *Wyeth* did *not* involve generic drugs, so it had no occasion to address Hatch-Waxman's textually manifest goal of promoting the interstate commercial sale of generic drugs that share a previously approved drug design in order to reduce healthcare costs. *Mensing did* involve generic drugs, and it explained in no uncertain terms that Hatch-Waxman's "special, and different, regulation of generic drugs" fulfilled that evident legislative objective by "allow[ing] the generic drug market to expand, [and] bringing more drugs more quickly and cheaply to the public. [D]ifferent federal statutes

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review of those issues at the behest of other persons may be found to be impliedly precluded.").

and regulations may, as here, lead to different pre-emption results." 131 S. Ct. at 2582.

Nor did *Wyeth* reject the foregoing historical analysis of Congress's delegation of withdrawal authority to FDA or its repeated extension of legal protections to parties aggrieved by FDA's exercise of that authority. Once again, *Wyeth* had no occasion to consider those specific textual provisions because they were not remotely implicated by the plaintiff's claim that Wyeth should have changed its product labeling unilaterally—as the Court held federal regulations specifically authorized Wyeth to do. *Wyeth*, 555 U.S. at 568-69; *see also id.* at 575 ("Wyeth relies not on any statement by Congress, but instead on the preamble to a 2006 FDA regulation governing the content and format of prescription drug labels."). That is why the Court repeatedly characterized FDA's congressionally delegated authority over branded drug labeling standards as establishing only a "floor" and not also (as Wyeth contended) a "ceiling." *Id.* at 573, 575, 577. And it is why the Court ultimately held only that "Wyeth has not persuaded us *that failure-to-warn claims like Levine's* obstruct the federal regulation of drug labeling," 555 U.S. at 581—not that any conceivable state-law claim (however outlandish and whatever its subject matter) comports with the FDCA.[12]

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[12] Indeed, *Wyeth*'s core holding was merely that FDA's *regulatory preamble* did not preempt state law failure-to-warn claims; as the Court explained, that preamble was not "a specific agency regulation bearing the force of law" and did "not merit deference," *id.* at 580, because FDA previously "cast federal labeling standards as a floor upon which States could

Wyeth thus offers no support for the First Circuit's radical conclusion that state-law juries are free to supplant FDA's statutorily delegated authority over the approval and withdrawal of drug designs from interstate commerce—much less for its apparent belief that state-law juries are free to exercise such authority despite failing to provide the specific statutory protections Congress granted parties affected by the exercise of such authority. Again, it is undisputed that the federal labeling and design requirements for generic drugs set both a "floor" and a "ceiling," rendering *Wyeth*'s assertions regarding congressional intent in the branded labeling context beside the point. Indeed, had *Wyeth* intended to go any further, it would have been entirely unnecessary for the Court to consider (at great length) whether the federal labeling standards

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build and repeatedly disclaimed any attempt to pre-empt failure-to-warn claims." *Id.* at 577-78 (discussing FDA, *Prescription Drug Product Labeling; Medication Guide Requirements—Final Rule*, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998)); *see also id.* at 582 (Breyer, J., concurring) (emphasizing "the Court's statement that we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law," noting that "state law will sometimes interfere with the FDA's desire to create a drug label containing a specific set of cautions and instructions," concluding "it is possible that such determinations would have pre-emptive effect," and reiterating that "such a regulation is not at issue in this case.") (internal citations and quotations omitted). Suffice it to say, Mutual's argument here is based on specific provisions of the FDCA that unquestionably bear the force of law, and FDA has *never* taken the position that federal design standards for generic drugs are merely a floor upon which the states are free to build.

were both a floor and a ceiling, and whether the CBE regulation did or did not permit Wyeth to change its product labeling without first securing FDA's prior approval; the simple (and far shorter) answer would have been that those questions were irrelevant because Wyeth could have pulled Phenergan® off the market if it wanted to avoid state tort liability.

At bottom, the sharp conflict between the stop-selling theory and Congress's textually evident purposes and objectives forecloses liability here.

CONCLUSION

The judgment should be reversed.

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Respectfully submitted,

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ADDENDUM A

United States Code Annotated

Title 21. Food and Drugs

Chapter 9. Federal Food, Drug and Cosmetics Act

Subchapter V. Drugs and Devices

Part A. Drugs and Devices

§ 355. New Drugs

Effective date: December 8, 2003

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the

application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A), and (G) any assessments required under section 355c of this title.

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which

information is required to be filed under paragraph (1) or subsection (c) of this section—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) Notice of opinion that patent is invalid or will not be infringed

(A) Agreement to give notice

An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) Timing of notice

An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the

notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) Recipients of notice

An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) Contents of notice

A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) of this section prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 262 of Title 42, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of Title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary

and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 262 of Title 42 (including all scientific and

medical matters, chemistry, manufacturing, and controls).

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) Approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) of this section applies, or

(B) Give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) of this section on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the

holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) of this section because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) of this section because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) of this section which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A) of this section:

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) of this section or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A) of this section, the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A) of this section, the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) of this section is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) of this section before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) of this section or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28, by an applicant referred to in subsection (b)(2) of this section for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was

dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) of this section for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall

review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) of this section and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) of this section or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of

reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) of this section before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under subsection (b) of this section after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A) of this section. The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) of this section for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three

years from the date of the approval of the application under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability [FN1] studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) of this section for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the

approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from September 24, 1984.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) of this section and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b) of this section, do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities

and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b) of this section; or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from

one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by

subsection (c) of this section was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) of this section with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) of this section or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the

Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

(f) Revocation of order refusing, withdrawing or suspending approval of application

Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) of this section refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Service of orders

Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) Appeal from order

An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of

Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of Title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the

United States upon certiorari or certification as provided in section 1254 of Title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section; and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a

"clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefore, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to

whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a

petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved

for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed

(i) Agreement to give notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) Timing of notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) Recipients of notice

An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by

the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice

A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence

udies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection

(including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title, or no petition to file an application for the drug with the

different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered

to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an

action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-day exclusivity period

(I) Effectiveness of application

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application

As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F)

or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of

the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market

The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) Withdrawal of application

The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval

The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements

for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner

The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant

If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and

conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the

list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(k) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) of this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order

with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) of this section shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(l) Public disclosure of safety and effectiveness data

Safety and effectiveness data and information which has been submitted in an application under subsection (b) of this section for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(1) if no work is being or will be undertaken to have the application approved,

(2) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(3) if approval of the application under subsection (c) of this section is withdrawn and all legal appeals have been exhausted,

(4) if the Secretary has determined that such drug is not a new drug, or

(5) upon the effective date of the approval of the first application under subsection (j) of this section which refers to such drug or upon the date upon which the approval of an application under subsection (j) of this section which refers to such drug could be made effective if such an application had been submitted.

(m) "Patent" defined

For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(n) Scientific advisory panels

(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under this section or section 262 of Title 42, the Secretary shall establish panels of experts or use panels of experts established before November 21, 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 394 of this title to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of

the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel

essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

(5) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this chapter and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including travel-time, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of Title 5, for persons in the Government service employed intermittently.

(7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions

and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

CHAP. 3915. —*An Act* For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of this Act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court.

SEC. 2. That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food or drugs which is adulterated or misbranded, within the meaning of this Act, is hereby prohibited; and any person who shall

ship or deliver for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign county, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such article so adulterated or misbranded within the meaning of this Act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods or drugs, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding two hundred dollars for the first offense, and upon conviction for each subsequent offense not exceeding three hundred dollars or be imprisoned not exceeding one year, or both, in the discretion of the court: *Provided*, That no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this provision shall not exempt said article from the

operation of any of the other provisions of the Act.

* * *

SEC. 4. That the examinations of specimens of foods and drugs shall be made in the Bureau of Chemistry of the Department of Agriculture, or under the direction and supervision of such Bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this Act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions for this Act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid.

SEC. 5. That is shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this

Act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided.

* * *

SEC. 10. That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one Sate, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however*, That upon the

payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

* * *

PUBLIC LAWS - CHS. 649, 653, 675 - JUNE 24, 25, 1938 [52 STAT.]

[CHAPTER 675]

AN ACT

To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I - SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

* * *

NEW DRUGS

SEC. 505 (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the

manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Secretary by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application.

(d) If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he

shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Secretary finds that the facts so require.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his principal place of business, or in the District Court of the United States for the District of Columbia, within sixty days after the entry of such order, a written petition praying that

the order of the Secretary be set aside. A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the record upon which the order complained of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure to do so. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Secretary shall be final, subject to review as provided in sections 128, 239, and 240 of the Judicial Code, as amended (U.S.C., 1934 ed., title 28, secs. 225, 346, and 347), and in section 7, as amended, of the Act

entitled "An Act to establish a Court of Appeals for the District of Columbia", approved February 9, 1893 (D.C. Code, title 18, sec. 26). The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

* * *

Public Law 87-781

AN ACT

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, effectiveness, and reliability of drugs, authorize standardization of drug names, and clarify and strengthen existing inspection authority; and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act, divided into titles and sections according to the following table of contents, may be cited as the "Drug Amendments of 1962".

* * *

EFFECTIVENESS AND SAFETY OF NEW DRUGS

SEC. 102. (a) (1) Section 201 (p) (1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (p)(1)), defining the term "new drug", is amended by (A) inserting therein, immediately after the words "to evaluate the safety", the words "and effectiveness", and (B) inserting therein, immediately after the words "as safe", the words "and effective".

(2) Section 201 (p)(2) of such Act (21 U.S.C. 321 (p)(2)) is amended by inserting therein, immediately after the word "safety", the words "and effectiveness".

(b) Section 505(b) of such Act (21 U.S.C. 355(b)) is amended by inserting therein, immediately after the words "is safe for use", the words "and whether such drug is effective in use".

(c) Section 505(d) of such Act (21 U.S.C. 355 (d)) is amended to read as follows:

"(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed,

recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

(d) Section 505(e) of such Act (21 U.S.C. 355(e)) is amended to read as follows:

"(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved,

evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (j), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated

together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packaging of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based."

* * *

NEW DRUG CLEARANCE PROCEDURE

SEC. 104. (a) Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a)), is amended to read as follows:

"(a) No personal shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug."

(b) Section 505(c) of such Act (21 U.S.C. 355(c)) is amended to read as follows:

"(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either -

"(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

"(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs."

(c) Section 505(f) of such Act (21 U.S.C. 355 (f)) is amended to read as follows:

"(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, with-drawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate."

(d)(1) The first four sentences of section 505(h) of such Act (21 U.S.C. 355(h)) are amended to read as follows: "An appeal may be taken by the

applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order."

(2) The ninth sentence of such section 505(h) is amended to read as follows: "The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code."

* * *

PUBLIC LAW 98-417 - SEPT. 24, 1984
98 STAT. 1585

Public Law 98-417
98th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Drug Price Competition and Patent Term Restoration Act of 1984".

TITLE I – ABBREVIATED NEW DRUG APPLICATIONS

Sec. 101. Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by redesignating subsection (j) as subsection (k) and inserting after subsection (i) the following:

"(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

"(2)(A) An abbreviated application for a new drug shall contain – "(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (6) (hereinafter in this subsection referred to as a 'listed drug');

"(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that

the active ingredient of the new drug is the same as that of the listed drug;

"(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

"(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

"(iii) information to show that the route of administration, the dosage form, and strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

"(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clasue (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C),

information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

"(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

"(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

"(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) –

"(I) that such patent information has not been filed,

"(II) that such patent has expired,

"(III) of the date on which such patent will expire, or

"(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

"(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a

use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

"(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

"(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

"(II) the holder of the approved application under subsection (b) for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

"(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

"(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

"(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds –

"(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

"(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

"(3) Subject to paragraph (4), the Secretary shall approve an application for a drug unless the Secretary finds –

"(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality and purity;

"(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

"(C)(i) if the listed drug has only one active ingredient, information submitted with the application

is insufficient to show that the active ingredient is the same as that of the listed drug;

"(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

"(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show –

"(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

"(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

"(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage from, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

"(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage

form, or strength was approved under paragraph (2)(C);

"(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage from, or strength which is not the same;

"(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

"(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

"(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or

(ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

"(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (5), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

"(J) the application does not meet any other requirement of paragraph (2)(A); or

"(K) the application contains an untrue statement of material fact.

"(4)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

"(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

"(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

"(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

"(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that –

"(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

"(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35, United States Code, or

"(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not

infringed, the approval shall be made effect on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, United States Code, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

"(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after –

"(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

"(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier

"(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within

thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs

"(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

"(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains

a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

"(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

"(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the

person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

"(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from the date of enactment of this subsection.

"(5) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended –

"(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

"(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary

determines that the withdrawal from sale is not for safety or effectiveness reasons.

"(6)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public –

"(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

"(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

"(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

"(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

"(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary the Secretary shall, in revisions made under clause (ii), include such information for such drug.

"(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

"(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (5) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list –

"(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (5), or

"(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

"(7) For purpose of this subsection:

"(A) The term 'bioavailability' means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

"(B) A drug shall be considered to be bioequivalent to a listed drug if –

"(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

"(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.".

* * *

111 STAT. 2296 PUBLIC LAW 105-115 NOV. 21, 1997

Public Law 105-115

105th Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

* * *

SEC. 119. CONTENT AND REVIEW OF APPLICATIONS.

(a) Section 505(b).—Section 505(b) (21 U.S.C. 355(b)) is amended by adding at the end of the following:

"(4)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

"(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of

an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

"C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

"(i) with the written agreement of the sponsor or applicant; or

"(ii) pursuant to a decision, made in accordance with the subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

"(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

"(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

"(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel nnless [sic] the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

"(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls.".

(b) Section 505(j).—

(1) Amendment.—Section 505(j) (21 U.S.C. 335(j)) is amended—

(A) by redesignating paragraphs (3) through (8) as paragraphs (4) through (9), respectively; and

(B) by adding after paragraph (2) the following:

"(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

"(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies.

Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

"(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

"(i) with the written agreement of the sponsor or applicant; or

"(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug ahs been identified after the testing has begun.

"(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

"(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

"(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing

division determines that a delay is necessary to assure the marketing of a safe and effective drug.

"(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).".

(2) Conforming Amendments.—Section 505(j) (21 U.S.C. 355(j)), as amended by paragraph (1), is further amended—

(A) in paragraph (2)(A)(i), by striking "(6)" and inserting "(7)";

(B) in paragraph (4) (as redesignated in paragraph (1)), by striking "(4)" and inserting "(5)";

(C) in paragraph (4)(l) (as redesignated in paragraph (1)), by striking "(5)" and inserting "(6)"; and

(D) in paragraph (7)(C) (as redesignated in paragraph (1)), by striking "(5)" each place it occurs and inserting "(6)".

* * *

ADDENDUM B

States That Apply Restatement (Second) of Torts § 402A, cmt. k

Ala.	*Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301 (Ala. 1984)
Ariz.	*Gaston v. Hunter*, 588 P.2d 326 (Ariz. Ct. App. 1978)
Ark.	*West v. Searle & Co.*, 806 S.W.2d 608 (Ark. 1991)
Cal.	*Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988)
Colo.	*Ortho Pharm. Corp. v. Heath*, 722 P.2d 410 (Colo. 1986) (en banc), *overruled on other grounds by Armentrout v. FMC Corp.*, 842 P.2d 175 (Colo. 1992) (en banc)
Conn.	*Hurley v. Heart Physicians, P.C.*, 898 A.2d 777 (Conn. 2006)
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Fla.	*Adams v. G.D. Searle & Co., Inc.*, 576 So. 2d 728 (Fla. Ct. App. 1991)
Ga.	*Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723 (Ga. App. 2003)
Haw.	*Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273 (Haw. 1992)
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Ind.	*Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541 (Ind. Ct. App. 1979)
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Kan.	*Savina v. Sterling Drug, Inc.*, 795 P.2d 915 (Kan. 1990)
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Mich.	*Nichols v. McNeilab, Inc.*, 850 F. Supp. 562 (E.D. Mich. 1993)
Minn.	*Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293 (D. Minn. 1988)
Miss.	*Bennett v. Madakasira*, 821 So. 2d 794 (Miss. 2002), *overruled on other grounds by Bennett v. Madakasira*, 821 So. 2d 794 (Miss. 2002)
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N.J.	N.J.S.A. §2A:58C-3(a)(3)
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N.Y.	*Martin v. Hacker*, 628 N.E.2d 1308 (N.Y. 1993)
N.C.	N.C. Gen. Stat. § 99B-6(d)
Ohio	Ohio Rev. Code Ann. § 2307.75(D)

Okla.	*Tansy v. Dacomed Corp.*, 890 P.2d 881 (Okla. 1994)
Or.	Or. Rev. Stat. § 30.920(3)
Pa.	*Lance v. Wyeth*, 4 A.3d 160 (Pa. Super. Ct. 2010)
R.I.	*Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775 (R.I. 1988)
S.C.	S.C. Code Ann. § 15-73-30
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Wyo.	*Jacobs v. Dista Prods. Co.*, 693 F. Supp. 1029 (D. Wyo. 1988)

RESPONDENT'S BRIEF

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IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Writ of Certiorari
to the United States Court of Appeals
for the First Circuit

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QUESTION PRESENTED

Whether federal law preempts the district court's judgment awarding compensatory damages to respondent for severe injuries resulting from use of a generic pain medication manufactured by petitioner.

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INTRODUCTION

Out of respect for state sovereignty and fundamental principles of federalism, this Court has established strict standards for determining when federal law displaces state law under the Supremacy Clause absent an express statement from Congress. State law directly conflicts with federal law, and is preempted, only when compliance with the laws of both sovereigns is physically impossible or when state law presents an unacceptable obstacle to Congress's objectives. Neither type of conflict is present here.

First, petitioner can comply with the district court's judgment without violating federal law. Under New Hampshire's law of strict products liability, a manufacturer of an unreasonably dangerous product – a product whose risks outweigh its benefits – is subject to liability for foreseeable injuries caused by that product. The New Hampshire Supreme Court has made clear that strict liability is not premised on any underlying standard of conduct or legal duty.

This case therefore differs fundamentally from the negligence-based failure-to-warn claims held preempted in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). In *PLIVA*, state law undisputedly required the manufacturers affirmatively to improve the drug's label. Here, however, the only state-law obligation is to compensate consumers for injuries caused by an unreasonably dangerous product. Nothing in federal law prohibits petitioner from paying compensatory damages to Ms. Bartlett.

Second, the judgment presents no obstacle to the fulfillment of Congress's purposes. The Federal Food, Drug, and Cosmetic Act ("FDCA") makes the Food and Drug Administration ("FDA") a gatekeeper,

charged with keeping unsafe and ineffective drugs out of interstate commerce. Requiring manufacturers to pay compensation for injuries that their drugs cause does not interfere with FDA's ability to perform that gatekeeping function.

In addition, nothing in the statute gives manufacturers a federal *right* to market FDA-approved drugs in interstate commerce, let alone a right to do so free from damages liability under state law. Nor does the statute support petitioner's and the government's contention that Congress intended to "establish[] both a floor and a ceiling for drug regulation." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). Rather, this case exemplifies why FDA has long regarded state tort actions as "a complementary form of drug regulation." *Id.* at 578. The litigation below unearthed important evidence about a dangerous drug, and the judgment provided compensation to a woman injured horribly by that drug.

STATEMENT

A. Statutory and Regulatory Background

1. With the emergence of centralized markets for drugs in the mid-nineteenth century came concerns about the spread of dangerous drugs. *See* Peter Barton Hutt et al., *Food and Drug Law* 7 (3d ed. 2007). Shortly thereafter, courts began to recognize common-law remedies for consumers injured by such drugs.[1]

In 1906, Congress enacted the first Federal Food and Drugs Act to "supplement[] the protection for

---

[1] *See, e.g.*, *Thomas v. Winchester*, 6 N.Y. 397, 409 (1852); *Fisher v. Golladay*, 38 Mo. App. 531, 1889 WL 174, at *3 (1889); *Marx v. Schultz*, 175 N.W. 182, 184 (Mich. 1919); *Napier v. Greenzweig*, 256 F. 196, 198 (2d Cir. 1919).

consumers already provided by state regulation and common-law liability." *Levine*, 555 U.S. at 566. In 1938, Congress enacted the FDCA "for the purposes of safeguarding the public health [and] preventing deceit upon the purchasing public." H.R. Rep. No. 75-2139, at 3 (1938).

The FDCA's fundamental provision – then, as now – bars a "new drug" from interstate commerce unless "an application" filed under the Act is "effective with respect to such drug." 21 U.S.C. § 355(a). Under the FDCA as originally enacted, FDA "had to prove harm to keep a drug out of the market," *Levine*, 555 U.S. at 567, and an application became effective after 60 days unless FDA took action, FDCA § 505(c), 52 Stat. 1052. By contrast, when Congress enacted the Drug Amendments of 1962 ("1962 Amendments"), it provided that an application would become effective only if FDA affirmatively "approve[d]" it. 1962 Amendments § 104(b), 76 Stat. 784.

Even as the 1962 Amendments strengthened FDA's premarket-review authority, Congress provided that they should not "be construed as invalidating" state laws "unless there is a direct and positive conflict between such amendments and such provision of State law." *Id.* § 202, 76 Stat. 793. State-law actions against drug manufacturers continued, with courts rejecting preemption defenses in the rare instances in which they were raised.[2] Many of those

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[2] "Courts that have considered the question have overwhelmingly held that FDA approval of a new drug application does not preempt state tort suits." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 343 (2008) (Ginsburg, J., dissenting); *see id.* at 340 n.11, 343 n.16 (collecting cases).

actions included claims that drugs were unreasonably dangerous.[3]

2. The premarket-review procedure established by the 1962 Amendments requires a manufacturer seeking to market a branded drug to submit a new drug application ("NDA"). *See* 21 U.S.C. § 355(b). FDA must approve an NDA unless it finds that the drug fails one of the enumerated statutory standards, which include requirements that an NDA contain "adequate tests by all methods reasonably applicable to show" that the drug is "safe for use," as well as "substantial evidence that the drug will have the effect it purports." 21 U.S.C. § 355(d).

In the decades following the 1962 Amendments, the "serious anti-competitive effects" of the NDA process became apparent. H.R. Rep. No. 98-857, pt. 2, at 4 (1984). Branded drugs often obtained "monopoly" status because competing manufacturers could typically secure approval for generic substitutes only by making "enormous expenditures of money" for "duplicative tests." *Id.* Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, often called the "Hatch-Waxman Act," "to make available more low cost generic drugs by establishing a generic drug approval procedure." H.R. Rep. No. 98-857, pt. 1, at 14 (1984). An abbreviated new drug application ("ANDA") under Hatch-

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[3] *See, e.g.*, *Hill v. Searle Labs.*, 884 F.2d 1064, 1069-70 (8th Cir. 1989); *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 657 (1st Cir. 1981); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 134-35 (3d Cir. 1973); *Leibowitz v. Ortho Pharm. Corp.*, 307 A.2d 449, 457-58 (Pa. Super. Ct. 1973) (per curiam); *see also Riegel*, 552 U.S. at 340 (Ginsburg, J., dissenting) ("[S]tate common-law claims for drug labeling and design defects . . . continued unabated despite . . . FDA regulation.").

Waxman, unlike an NDA, need not contain clinical evidence of the drug's safety, but must demonstrate the generic drug's equivalence to a previously approved branded drug. *See* 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 320.1(c).

B. Factual Background

1. Sulindac is a non-steroidal anti-inflammatory drug ("NSAID") generally intended to relieve muscle pain. *See* App. 3a; JA553. Sulindac is "known to cause" a condition called "Stevens-Johnson Syndrome and its more generic cousin toxic epidermal necrolysis ('SJS/TEN')," App. 3a, a severe adverse reaction involving extensive loss of skin.

In 1978, FDA approved an NDA for the branded version of sulindac, called Clinoril. JA61 (¶ 22). In 1991, FDA determined that petitioner's generic version of sulindac was equivalent to Clinoril and approved petitioner's ANDA. *See* App. 144a-145a; 21 C.F.R. § 320.1(c). When FDA approved the Clinoril NDA, available "clinical studies" suggested that its side effects were "relatively mild." JA596 (Glen D. Park et al., *Serious Adverse Reactions Associated With Sulindac*, 142 Arch. Intern. Med. 1292 (July 1982)). Only later, as post-marketing "reports began to accumulate," did the drug's serious SJS/TEN risks emerge. *Id.* The record contains no evidence that FDA considered those risks in approving either Clinoril or petitioner's ANDA.

In February 2005, private citizens petitioned FDA to conduct a "risk assessment of SJS and TEN associated with ibuprofen," which (like sulindac) is an

NSAID.[4] The Citizen Petition requested that ibuprofen's labeling "include a specific warning" about SJS/TEN. Citizen Petition at 1-2. The Petition observed that the "ca[us]al relationship between NSAIDs" and SJS/TEN "is well-documented," and it supplied a table of "accumulated evidence" from the medical literature. *Id.* at 7, 10.

In April 2005, FDA staff issued a memorandum addressing cardiovascular risks in NSAIDs. That memorandum included a footnote stating that the Citizen Petition was "under review" and that FDA had "not reached a decision on the requested actions." JA580 n.8. The memorandum noted the lack of reliable data indicating that any one NSAID provided "greater relief of pain and inflammation" than any other. JA559. It further observed that adverse event reporting suggested that one NSAID, Bextra, was "associated with an increased rate of serious and potentially life-threatening skin reactions," including SJS/TEN. *Id.* Given the "absence of any demonstrated advantage over other NSAIDs," the staff recommended that Bextra be withdrawn from the market. JA559-60; *see* JA588.

More than a year later, FDA granted in part and denied in part the Citizen Petition. FDA agreed that labeling revisions were "necessary to make more explicit the risks associated with SJS and TEN," and it recommended that "all NSAID[]" manufacturers specifically identify SJS/TEN in the "Warnings" section

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[4] Citizen Petition at 1, FDA Docket No. 2005P-0072/CP1 (Feb. 15, 2005) ("Citizen Petition"), http://www.fda.gov/ohrms/dockets/dockets/05p0072/05p-0072-cp00001-01-vol1.pdf.

of the prescription labels.[5] FDA also noted that it had recently made a "comprehensive effort" to educate the public about SJS/TEN. 2006 Letter at 6. Given those efforts, FDA rejected the Citizen Petition's request for an even stronger "boxed warning" for ibuprofen products. *Id.* at 8. Neither the 2005 memorandum nor the 2006 Letter mentioned sulindac.

Pursuant to FDA's recommendation, petitioner updated the "Warnings" section of its label to refer explicitly to SJS/TEN, JA555; previously, it had been listed only as a possible adverse reaction, JA554. Sulindac remains on the market today with that strengthened warning. JA354.

2. In December 2004 – before FDA had received the Citizen Petition or taken any action regarding SJS/TEN – Karen Bartlett visited her doctor complaining of shoulder pain. JA450-51. Her physician prescribed sulindac "under the brand-name Clinoril," and her "pharmacist dispensed generic sulindac" manufactured by petitioner. App. 3a.

"The consequences were," in the First Circuit's words, "disastrous." *Id.* In early 2005, Ms. Bartlett developed SJS/TEN. *Id.* "TEN is diagnosed when 30 percent or more of the outer skin layer on a patient's total body surface area has deteriorated, been burned off or turned into an open wound." *Id.* In Ms. Bartlett's case, "the percentage rose to 60-65 percent of her bod[illegible]." *Id.*

Ms. Bartlett's injuries, which the First Circuit characterized as "truly horrific," App. 22a, are pic-

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[5] Decision Letter at 7, FDA Docket No. 2005P-0072/CP1 (June 22, 2006) ("2006 Letter"), http://www.fda.gov/ohrms/dockets/dockets/05p0072/05p-0072-pav0001-vol1.pdf.

tured in part at JA640-44. The pictures reveal some of the physical manifestations of Ms. Bartlett's injuries: the burns (JA641), disfigurement (JA643), and eye damage that has left her legally blind (JA640, 644). But no picture can convey fully Ms. Bartlett's experience with SJS/TEN, which her burn surgeon described as "'hell on earth.'" App. 23a. She "spent months in a medically-induced coma," spent 100 days in five different hospitals, was fed by tube for a year, and "endured two major septic shock episodes." App. 22a-23a; C.A. App. 2809-29. "She suffered through 12 eye surgeries and has many more ahead of her." App. 23a. She "cannot eat normally due to esophageal burns, cannot have sexual relations due to vaginal injuries, and cannot engage in aerobic activities due to lung injuries." *Id.* Nor will she likely ever be able to return to work, because she cannot drive or read. JA440. As the district court stated, "[n]o one who witnessed the trial in this case could deny the horror" that Ms. Bartlett has suffered. App. 101a.

C. Proceedings Below

1. Ms. Bartlett filed suit against petitioner in New Hampshire Superior Court. JA34-35. After petitioner removed the action to federal court, Ms. Bartlett filed an amended complaint alleging various state-law claims. JA81-124. One claim alleged that petitioner had breached its "duty to warn" about sulindac's risks, JA102 (¶ 44), while another alleged that petitioner was strictly liable for selling an "unreasonably dangerous" drug, JA106 (¶ 57). Ms. Bartlett sought only damages, not an injunction requiring petitioner to change sulindac's design or label. JA120-22.

The court granted summary judgment for petitioner on the failure-to-warn claims. App. 115a-116a.

The court concluded, in light of the testimony of Ms. Bartlett's doctor that he had not read the drug's label, that Ms. Bartlett could not prove that a stronger warning would have avoided her injury. App. 117a-121a. In contrast, the court denied petitioner's motion as to Ms. Bartlett's "defective design claims." App. 128a. Although petitioner argued that those claims were "really failure-to-warn claims," the court held that was "not accurate" and that Ms. Bartlett's design-defect allegations were "independent of any inadequacy in the product's safety warning." App. 124a-125a.[6]

The court noted, however, that petitioner could still "use Sulindac's safety warning as part of its defense." App. 125a. New Hampshire has adopted the theory of strict products liability set forth in Section 402A of the Restatement (Second) of Torts (1965). *See id.* The court observed that petitioner might "be able to avoid liability" under comment k to Section 402A if it could prove, as an "affirmative defense," that "Sulindac is unavoidably unsafe and had an adequate safety warning." App. 128a. But petitioner subsequently abandoned its "comment k" defense "on the eve of trial, without explanation." App. 36a. With that defense "out of the case, the adequacy of sulindac's warning . . . was no longer an issue for trial." *Id.*

2.a. In August–September 2010, the district court held a 14-day trial on Ms. Bartlett's strict-liability design-defect claim. Her experts presented a "litany of specific facts, most of them drawn directly from the medical literature or published FDA analyses,"

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[6] The court subsequently granted petitioner summary judgment on Ms. Bartlett's negligence claims. JA317.

demonstrating that sulindac's risks outweigh its benefits. App. 42a. The evidence showed that, although all NSAIDs carry risks of SJS/TEN, *see* App. 42a-43a, FDA received more adverse event reports of SJS/TEN attributed to sulindac than "any other NSAID on the market." App. 44a. Moreover, an unpublished manuscript ("Pharmacia Report," *see* JA626-34) drafted by petitioner's expert indicated that sulindac's adjusted reporting rate of SJS/TEN from 1980-1997 "was the highest of any NSAID." App. 45a. Those facts made sulindac's "'risk/benefit profile'" comparable to that of Bextra, whose removal from the market FDA had recommended based on similar reporting data. App. 46a. One of Ms. Bartlett's experts testified that the Pharmacia Report's author had never given it to FDA, and that FDA was unaware of sulindac's adjusted reporting rate of SJS/TEN. JA429-31.

The testimony further indicated that sulindac was unlike a drug that is the "only one available . . . to cure a cancer." 8/24/2010 p.m. Tr. 12:23-24. Rather, sulindac was prescribed for shoulder pain, and the evidence established that "[no] one NSAID – including sulindac – provides greater relief of pain and inflammation than other NSAIDs." App. 46a; *see* JA559. Tylenol and aspirin, the evidence showed, "carry no risk of SJS/TEN" and are "equally effective as sulindac" in treating the "shoulder pain" that Ms. Bartlett experienced. App. 47a. Given those safer alternatives, an expert opined that sulindac is "unreasonably dangerous" to the public as a whole and thus "shouldn't be on the market." 8/24/2010 p.m. Tr. 29:20-21.

Petitioner had designated its own expert on that topic, as well as other witnesses. *See* App. 5a. But

petitioner "chose not to call any of its own witnesses at trial, foregoing the opportunity to rebut Bartlett's evidence and put sulindac in a better light." App. 30a-31a.

b. The district court instructed the jury that sulindac was "defective as designed if the magnitude of the danger outweighs the utility or usefulness of the product." JA513. The relevant inquiry was not whether sulindac was beneficial for Ms. Bartlett in particular; the court instructed the jury to "consider the usefulness and desirability of the product to the public as a whole." *Id.* The court also explained that the jury could find sulindac "unreasonably dangerous" even without any "evidence of an alternative design that could have made the product safer." *Id.*

The instructions also required Ms. Bartlett to prove that sulindac was "unreasonably dangerous even with its warning" and allowed the jury to consider whether sulindac's warning was "effective to avoid [any] unreasonable danger." JA513-14. But the court emphasized that the "claim is focused on the product Sulindac and whether its design was in a defective condition," not on "[petitioner's] conduct other than selling Sulindac." 9/2/2010 p.m. Tr. 99:9-14. The court thus instructed the jury that "whether [petitioner] knew of Sulindac's safety risks or any of [its] conduct in seeking or responding to such knowledge is not an issue in this case" and that the jury "should put [those considerations] out of your mind." *Id.* at 99:15-20.

Finally, the jury was instructed that, if it found petitioner liable, it "should award a sum of money which will fairly compensate her for her injuries." JA519-20. The jury was "not permitted to award punitive damages or any other money damages for the

purpose of punishing [petitioner] or . . . preventing [petitioner] and others from similar conduct." JA522.

c. The jury rendered a verdict for Ms. Bartlett and awarded $21.06 million in compensatory damages. JA376-77. The district court denied petitioner's motions for a new trial and for judgment as a matter of law. App. 29a-103a. Relevant here, the court first rejected petitioner's argument that federal law preempted the damages judgment because the jury had "'second-guess[ed]' the FDA's risk/benefit analysis" of sulindac. App. 69a. The court noted that Ms. Bartlett's claim had much "in common with" *Levine*, in which this Court explained that "'state law offers an additional, and important, layer of consumer protection that complements FDA regulation.'" App. 70a (quoting *Levine*, 555 U.S. at 579).

The court also rejected petitioner's argument that federal law prohibited it from complying with the judgment. App. 72a-73a. It observed that petitioner was held liable not "for failing to change sulindac's design" but "for selling an unreasonably dangerous product." App. 72a. It further stated that New Hampshire law requires "manufacturers [to] compensate consumers for the damage caused by unreasonably dangerous products, not necessarily that they remove such products from the market." *Id.* (internal quotations omitted). Because "[f]ederal law did not require [petitioner] to sell sulindac," and certainly did not forbid it from paying damages, the court concluded that "it was not 'impossible' for [petitioner] to comply with both federal and state law." *Id.*

3. The First Circuit affirmed. Writing for the court, Judge Boudin upheld the district court's conclusion that compliance with New Hampshire law

was not impossible, reasoning that petitioner could "certainly" comply with both federal and state law by "choos[ing] not to make [sulindac] at all." App. 10a.

The court explained that *PLIVA* did not require a different result. There, this Court held that federal law "preempts failure-to-warn claims against generic drug manufacturers" because those manufacturers "cannot unilaterally change their labels" under federal law, and thus cannot comply with state-law duties to provide a stronger warning. App. 9a-10a. Here, however, the manufacturer can comply with state law consistent with federal law: although "the generic maker has no choice as to label," "the decision to make the drug and market [sulindac] in New Hampshire is wholly its own." App. 10a-11a.

The First Circuit also agreed that Ms. Bartlett's damages judgment posed no obstacle to any congressional purpose. In so concluding, it relied on *Levine*'s holding "that 'Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness' and that state law serves as a 'complementary form of drug regulation.'" App. 9a (quoting *Levine*, 555 U.S. at 575, 578) (citation omitted).

SUMMARY OF ARGUMENT

I. Compliance with the district court's judgment and federal law is not physically impossible.

A. Federal law permits petitioner to comply with the judgment by compensating Ms. Bartlett for her injuries. New Hampshire law requires nothing more of petitioner. The New Hampshire Supreme Court has made clear that strict products liability is not premised on any legal duty to alter a product's design. Under longstanding federalism principles, this Court is bound by the state supreme court's authoritative construction of state law.

PLIVA involved fundamentally different claims. The failure-to-warn claims in *PLIVA* rested on negligence principles, and all parties agreed that the manufacturers' state-law duty was to improve the labels affixed to their generic drug. *PLIVA*'s holding that compliance with that affirmative duty was impossible under federal law does not support preemption of Ms. Bartlett's claim, which involved no similar duty.

Nor do the express-preemption cases on which petitioner relies support finding implied-conflict preemption here. Those cases hold only that the term "requirement" in an express-preemption provision signals Congress's intent to displace common-law claims. Congress has not expressly preempted tort claims against prescription-drug manufacturers, and there is no warrant to treat the reach of *implied* preemption as broadly as *express* preemption.

B. Petitioner failed to preserve the argument that the district court's judgment is preempted because it was premised on a failure to improve sulindac's label.

Regardless, in New Hampshire, strict liability for selling an unreasonably dangerous product is not based on a duty to improve the product's warning. And in this case petitioner's withdrawal of its "comment k" defense meant that the adequacy of sulindac's label was not even an issue at trial. Moreover, petitioner cannot claim that the judgment was premised on a failure to improve sulindac's labeling, because petitioner cannot show that it would have avoided liability had sulindac carried a stronger warning of SJS/TEN.

C. Even if the judgment were premised on an underlying duty not to sell sulindac, nothing in federal law would prohibit compliance with that duty. Petitioner derides the First Circuit's so-called "stop-selling theory," but the court was correct that federal law permits compliance with a state-law duty not to sell an unreasonably dangerous drug. Contrary to petitioner's claim, that reasoning creates no conflict with *PLIVA*, because withdrawing the product offered only an indirect means of avoiding future liability in that case. It was not the act – changing a warning label in contravention of federal labeling rules – required by the state-law duty.

II. Petitioner's obstacle-preemption argument, which it did not raise in the petition, has no merit.

A. State damages actions complement federal drug regulation by compensating injured consumers and exposing hidden dangers. Ms. Bartlett's action did both. Reversal would not only thwart the FDCA's core purpose of consumer protection, but also extinguish the only remaining avenue of judicial relief for patients injured by generic drugs.

B. Petitioner's argument that FDA approval of a drug impliedly immunizes its manufacturer from

strict-liability claims lacks any statutory basis. FDA's function under the FDCA is to screen dangerous drugs from interstate commerce. The statute makes clear that initial FDA approval removes a barrier to marketing but provides no federal *right* to sell a drug. Damages actions do not interfere with FDA's ability to perform its gatekeeping function.

C. The government's asserted conflict between the district court's judgment and FDA regulation is even less persuasive. The government's newly minted preemption position has no grounding in any lawful regulation and represents yet another inexplicable departure from FDA's previous positions. As in *Levine*, the government's brief deserves no weight.

The government also provides no support for its premise that strict-liability claims will deprive patients of access to FDA-approved drugs. Given that such claims have existed for decades, the lack of evidence weighs heavily against the government's position.

The government's assertion that the jury here "second-guessed" FDA also misstates the record. FDA was never presented with the critical data on which Ms. Bartlett relied at trial. And, even if FDA had access to those data, there is no evidence the agency actually considered them.

D. The Hatch-Waxman Act, like the FDCA, evinces no intent to preempt state-law claims. Hatch-Waxman aims not to maximize the sale of generic drugs in all circumstances at all costs, but to minimize federal regulatory obstacles to generic drug development. State-law damages actions pose no conflict with that narrow purpose.

III. Even if the Court were to accept the government's new theory – which petitioner did not raise

below – that state law is preempted unless the plaintiff proves the drug was misbranded under federal law, the Court should nonetheless affirm. Sulindac was misbranded under federal law because the evidence at trial showed that sulindac was "'dangerous to health' when used as provided in the labeling." U.S. Br. 23 (quoting 21 U.S.C. § 352(j)).

ARGUMENT

Analysis of petitioner's conflict-preemption defense begins with the "two cornerstones" of this Court's "pre-emption jurisprudence." *Levine*, 555 U.S. at 565. First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Id.* (internal quotations omitted). Second, this Court presumes that Congress did not supplant the "historic police powers of the States" unless it made such a purpose "clear and manifest." *Id.* (internal quotations omitted).

Petitioner must demonstrate an "actual conflict," *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (internal quotations omitted), between federal law and New Hampshire law "strong enough to overcome the presumption" that Congress intended them to "coexist," *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985). An actual conflict exists when "it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Sprietsma*, 537 U.S. at 64 (internal quotations and citation omitted). Petitioner demonstrates neither type of conflict.

I. PETITIONER CAN COMPLY WITH THE DISTRICT COURT'S JUDGMENT AND FEDERAL LAW

Petitioner's first theory (at 29-45) is that compliance with the district court's judgment and federal law is impossible. "Impossibility pre-emption is a demanding defense," *Levine*, 555 U.S. at 573, which this Court has applied only in "very narrow" circumstances, *id.* at 590 (Thomas, J., concurring in the judgment). Petitioner must show that compliance with federal and state law is a "physical impossibility." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

A. The Judgment Is Not Premised On A Duty To Change Sulindac's Design

Petitioner argues (at 42-43) that compliance with federal and state law is physically impossible because New Hampshire law requires it to change the design of its generic drug sulindac, whereas federal law forbids it from doing so. That argument fails. Under the well-settled New Hampshire law applied in this case, a damages judgment based on strict products liability does not require a manufacturer to alter its product.

1. New Hampshire law obligates sellers of unreasonably dangerous products to compensate injured consumers, not to redesign their products

a. New Hampshire has adopted the "doctrine of strict liability of manufacturers for product defects in section 402A(1) of the *Restatement (Second) of Torts*." *Kelleher v. Marvin Lumber & Cedar Co.*, 891 A.2d 477, 492 (N.H. 2005). Under that standard, "'[o]ne who sells any product in a defective condition unreasonably dangerous . . . is subject to liability for the

physical harm thereby caused.'" *Id.* (quoting Restatement (Second) of Torts § 402A(1)) (emphasis omitted).

Two key features of New Hampshire's law of strict products liability establish that it imposes no duty on manufacturers to redesign their products. *First*, the New Hampshire Supreme Court has made clear that strict liability is not premised on the "violation" of any underlying "common law or statutory duty." *Bagley v. Controlled Env't Corp.*, 503 A.2d 823, 825 (N.H. 1986) (Souter, J.). In fact, the very essence of strict liability is the possibility of "liability absent proof of a violation of a legal duty." *Royer v. Catholic Med. Ctr.*, 741 A.2d 74, 76 (N.H. 1999). Untethered from traditional tort duties, strict liability simply redresses injuries; it does not punish a manufacturer for "depart[ing]" from any "required standard of conduct." *LeFavor v. Ford*, 604 A.2d 570, 572 (N.H. 1992).

Strict liability imposes no substantive duties on manufacturers because its purpose is compensatory, not regulatory. As it became apparent that many "products contain chemical compounds" whose "side effects . . . cannot be anticipated," New Hampshire courts concluded that "the risk of liability is best borne by the companies that profited from their sale, rather than by the unfortunate individual consumers" who suffered from their side effects. *Heath v. Sears, Roebuck & Co.*, 464 A.2d 288, 293 (N.H. 1983).[7] In negligence cases, however, the "burden" of

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[7] *Heath* noted that "[d]eterrence is also a valid consideration" justifying strict liability, for, "without the stimulus of plaintiffs' products liability actions, the incentive to improve products . . . would not exist." 464 A.2d at 293. But the state supreme court has subsequently confirmed that strict liability is not intended,

"establish[ing] traditional legal fault" on the part of manufacturers frequently deprived injured consumers of any remedy. *Bagley*, 503 A.2d at 826. Strict liability eliminates that burden when the plaintiff can show that a product's risks outweigh its benefits, requiring a manufacturer to pay compensatory damages even absent "traditional legal fault." *Id.*[8] It thus "offer[s] relief" to injured consumers who cannot "show that a ... duty of care ha[s] been breached." *Waid v. Ford Motor Co.*, 484 A.2d 1152, 1155 (N.H. 1984).

Moreover, New Hampshire courts award only compensatory damages in strict-liability (indeed, all tort) cases. "Punitive damages are not allowed in New Hampshire," and civil remedies may not aim to "'warn[]'" or "'deter'" defendants. *Stewart v. Bader*, 907 A.2d 931, 943 (N.H. 2006) (quoting *Aubert v. Aubert*, 529 A.2d 909, 914 (N.H. 1987)). Consistent with that principle, the district court here forbade the jury from awarding any "damages for the purpose of ... preventing [petitioner] and others from similar conduct." JA522. The damages award thus "com-

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nor does it function, as a tool for coercing changes in behavior. *See infra* pp. 20-21.

[8] An early case stated that "strict liability is not a no-fault system of compensation" that wholly abolishes the "principle that fault and responsibility are elements of our legal system." *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 845-46 (N.H. 1978). The New Hampshire Supreme Court later clarified that the role of "fault" in strict liability is not to enforce substantive duties on manufacturers, but to shield manufacturers from the financial burden of acting as blanket "insurers of their products." *Price v. BIC Corp.*, 702 A.2d 330, 333 (N.H. 1997). Hence, the only "fault" in a strict-liability case is the sale of an unreasonably dangerous product whose risks outweigh its benefits.

pensate[d]" Ms. Bartlett for "her injuries," JA519-20; it explicitly was *not* intended to coerce petitioner into redesigning its drug. *Cf. Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 275 n.3 (1984) (Powell, J., dissenting) (calling the "distinction" between compensatory and punitive damages "of major importance" and discerning "no element of regulation when compensatory damages are awarded").

Second, strict liability in New Hampshire is not premised on any duty to improve a product's design because the existence of a better design is not an element of a strict-liability claim. *See Kelleher*, 891 A.2d at 492 ("[T]he plaintiff is not required to present evidence of a safer alternative design."); App. 58a-61a. Instead, liability turns on whether a product is "unreasonably dangerous" under New Hampshire's "risk-utility balancing test." *Price*, 702 A.2d at 332. That test calls for an assessment whether "'the magnitude of the danger outweighs the utility of the product.'" *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001) (quoting W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* 699 (5th ed. 1984)).[9]

The outcome of that risk-utility balancing does not reflect any opinion about "the care exercised" by the manufacturer "to design a safe product." *Chellman v. Saab Scania AB*, 637 A.2d 148, 150 (N.H. 1993). Indeed, the "focus" of strict liability is not "on the

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[9] The risk-utility test involves a "'multifaceted balancing process,'" in which a possible design improvement is "neither a controlling factor nor an essential element that must be proved in every case." *Vautour*, 784 A.2d at 1182, 1183 (quoting *Thibault*, 395 A.2d at 847). It was not a factor here: sulindac "is a one-molecule drug" that cannot even theoretically be "made in a different and safer form." App. 6a.

conduct of the manufacturer" at all, but "on whether the design itself was unreasonably dangerous." *Connelly v. Hyundai Motor Co.*, 351 F.3d 535, 542 (1st Cir. 2003) (internal quotations omitted). Because a manufacturer can be held strictly liable "even though [it] exercised the highest degree of care," *Bolduc v. Herbert Schneider Corp.*, 374 A.2d 1187, 1189 (N.H. 1977), strict liability is not based on violation of any duty to design a safer product.

b. Although petitioner argues repeatedly that "respondent's tort claim" "embodie[s]" a "state design requirement," Pet. Br. 30; *see id.* at 42-43, it makes virtually no effort to ground that erroneous contention in New Hampshire cases. Citing an isolated snippet from a single decision, petitioner incorrectly asserts that New Hampshire law imposes a "basic duty . . . to 'design [its drug] reasonably safely for the uses [Mutual] can foresee.'" *Id.* at 42 (quoting *Thibault*, 395 A.2d at 847) (brackets added by petitioner).

But *Thibault* stated merely that a plaintiff's burden to "prove that . . . his use of the product was foreseeable by the manufacturer" is "predicated on the manufacturer's duty to design his product reasonably safely for the uses which he can foresee." 395 A.2d at 847. That statement *limited* manufacturers' liability to cases involving foreseeable uses of their products; it did not impose on manufacturers any free-standing duty of care. Indeed, in discussing whether a product poses unreasonable dangers in the first place – the element at issue here – *Thibault* did not reference any affirmative duty to design safe products. *See id.* at 846. And the New Hampshire Supreme Court has confirmed before and after *Thibault* that strict liability is not premised on any "violation of a common law

. . . duty." *Bagley*, 503 A.2d at 825; *see Kelton v. Hollis Ranch, LLC*, 927 A.2d 1243, 1246 (N.H. 2007); *LeFavor*, 604 A.2d at 572; *Moulton v. Groveton Papers Co.*, 289 A.2d 68, 71 (N.H. 1972).

2. The New Hampshire Supreme Court's articulation of state law controls here

This Court is bound by the New Hampshire Supreme Court's articulation of New Hampshire law. It is fundamental to "the federal design" that "federal and state courts" exist not in "competition and conflict," but as "complementary systems for administering justice in our Nation." *Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 586 (1999). Consistent with that bedrock principle, a "State's highest court is unquestionably the ultimate expositor of state law." *Riley v. Kennedy*, 553 U.S. 406, 425 (2008) (internal quotations and brackets omitted). Thus, this Court has long considered itself "bound to accept the interpretation of [state] law" provided "by the highest court of the State." *Hortonville Joint Sch. Dist. No. 1 v. Hortonville Educ. Ass'n*, 426 U.S. 482, 488 (1976).

This Court's practice of deferring to a State's highest court's construction of state law extends fully to the preemption context. *See Levine*, 555 U.S. at 565 (relying on the Vermont Supreme Court's definition of the "state-law duty at issue"); *Perez v. Campbell*, 402 U.S. 637, 644 (1971) (Court was "bound" by Arizona's "construction of its legislation"). In fact, the danger that a finding of preemption will trample on a State's police powers makes such deference all the more important. *Cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (emphasizing that preemption analysis must account for "federalism concerns"); *Levine*, 555 U.S. at 583-84 (Thomas, J., concurring in the judgment). Given the vital federalism interests at

stake, this Court should avoid any "interference with a state supreme court's ability to determine the content of state law." *Riley*, 553 U.S. at 427.[10]

* * *

Applying the principles of New Hampshire law described above, the properly instructed jury found that sulindac's risks outweighed its benefits. *See* App. 30a. That finding imposed only one obligation on petitioner: once the jury found that Ms. Bartlett proved that sulindac's risks outweighed its benefits based on the evidence adduced at trial, petitioner was required to compensate Ms. Bartlett for the injuries that sulindac caused her. As the district court explained, petitioner "was not held liable for failing to change sulindac's design; it was held liable for selling an unreasonably dangerous product." App. 72a.

3. *PLIVA* addressed a fundamentally different kind of common-law claim

Petitioner's main argument (at 29) is that "there is no principled basis for reaching a different result here than in [*PLIVA*]." New Hampshire strict-liability law, however, differs fundamentally from the state law at issue in *PLIVA*.

PLIVA addressed whether federal law preempted state negligence claims brought by injured patients

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[10] Although the New Hampshire Supreme Court has made clear that strict liability is not based on an underlying duty to modify the product, if this Court perceives any uncertainty regarding the content of state law, the appropriate course would be to certify the question to the state supreme court. *See* N.H. Sup. Ct. R. 34; *see also, e.g.*, *United States v. Juvenile Male*, 130 S. Ct. 2518, 2520 (2010); *Fiore v. White*, 528 U.S. 23, 29 (1999) (certifying question to State's highest court where answer would "help determine the proper state-law predicate for our determination of the federal constitutional questions raised").

against manufacturers of generic metoclopramide. *See* 131 S. Ct. at 2572. This Court began its preemption analysis by "identifying the state tort duties" at issue. *Id.* at 2573. That identification was straightforward: the patients alleged that the manufacturers "were liable under state tort law (specifically, that of Minnesota and Louisiana) for failing to provide adequate warning labels" warning of the risk of tardive dyskinesia. *Id.* The parties "did not dispute that," under the facts alleged by the plaintiffs, "state law required the Manufacturers to use a different, safer label." *Id.* at 2574.[11]

The parties' agreement in *PLIVA* obviated any need for a searching analysis of the relevant state-law duties. This Court, after all, is an "'arbiter[] of legal questions presented and argued by the parties before [it],'" and it generally refrains from deciding issues without "the benefit of briefing by the parties." *NASA v. Nelson*, 131 S. Ct. 746, 756 n.10 (2011) (quoting *Carducci v. Regan*, 714 F.2d 171, 177 (D.C. Cir. 1983) (Scalia, J.)). Because the parties in *PLIVA* agreed about the underlying content of state law, the Court accepted that "state law imposed on the Manu-

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[11] Given the plaintiffs' concession about the state-law duties, it makes no difference that the original complaints in *PLIVA* contained design-defect claims. *Cf.* Pet. Br. 31. As the case came to this Court, all the claims undisputedly rested on the manufacturers' duty to provide an adequate label. *See Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010) (characterizing the "one issue on appeal" as whether the FDCA preempts "failure-to-warn claims"), *rev'd*, *PLIVA*, *supra*; *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009) (noting that Mensing did "not challenge[] the district court's characterization" that "all" her claims "at the core . . . assert[ed] failure to warn") (internal quotations omitted), *rev'd*, *PLIVA*, *supra*.

facturers a duty to attach a safer label" to metoclopramide. 131 S. Ct. at 2578.[12]

PLIVA thus turned on whether federal law permitted the manufacturers to comply with that undisputed state-law duty to strengthen the warnings on their drug labels. *See id.* at 2574-77. The Court held that it did not. *Id.* at 2577 (federal law "prevented the Manufacturers from independently changing their generic drugs' safety labels"). Thus, when the Court "compare[d]" the manufacturers' duties under "federal and state law," it concluded that the manufacturers could not possibly "comply with both [the] state and federal requirements." *Id.* at 2573, 2577 (internal quotations omitted). That conclusion flowed directly from the parties' mutual characterization of the state-law duty at issue: had the manufacturers "independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id.* at 2578.

In short, *PLIVA* holds that federal law preempts common-law claims against generic drug manufacturers based on a duty, rooted in negligence, to provide a safer label. It does not address whether

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[12] The Court's understanding of Minnesota and Louisiana law also comported with the statements of those States' highest courts. In Minnesota, a manufacturer's "'knowledge of danger to users'" gives rise to a "'duty to give warning of such dangers.'" *PLIVA*, 131 S. Ct. at 2573 (quoting *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn. 1977)). That duty is an affirmative obligation "based on a concept of negligence." *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 622 (Minn. 1984). Louisiana law likewise imposes on manufacturers a "duty . . . to use reasonable care to provide an adequate warning." *Marks v. OHMEDA, Inc.*, 871 So. 2d 1148, 1155 (La. Ct. App. 2004) (cited by *PLIVA*, 131 S. Ct. at 2573) (internal quotations omitted).

strict-liability claims that involve no such duty are preempted.[13]

4. *Riegel* and *Cipollone* do not support disregarding the New Hampshire Supreme Court's interpretation of state law

Relying on *Riegel* and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), petitioner contends that "common-law liability is" always "premised on the existence of a legal duty" to take some affirmative action. Pet. Br. 41 (internal quotations omitted). But those cases construed *express*-preemption clauses in federal statutes; neither addressed *implied* conflict preemption of state law.

a. *Riegel* and *Cipollone* held that Congress's use of the term "requirement" in an express-preemption provision signals its intent to capture duties imposed by state common law. *See Riegel*, 552 U.S. at 323-25; *Cipollone*, 505 U.S. at 520-24 (plurality). "Congress," the Court explained in *Riegel*, "is entitled to know what meaning this Court will assign to terms regularly used in its enactments." 552 U.S. at 324. Thus, the Court concluded that, "[a]bsent other indication," Congress's explicit "reference to a State's 'requirements' includes its common-law duties." *Id.*

That statutory-interpretation holding does not support finding implied conflict preemption here. It is one thing to interpret the word "requirement" in a statutory phrase as conveying Congress's explicit intent to preempt common-law duties; it is quite an-

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[13] *See Halperin v. Merck, Sharpe & Dohme Corp.*, No. 11-cv-9076, 2012 WL 1204728, at *3 (N.D. Ill. Apr. 10, 2012) (*PLIVA* does not "address strict liability design defect claims" and therefore does not require preemption of claims involving no substantive "state law duty").

other to *infer* conflict preemption where no express-preemption provision evidences Congress's intent to displace state law. *Riegel* made clear that its holding could not justify the latter. Had "Congress wanted" the regimes for medical devices and prescription drugs "to be alike," it "could have applied the pre-emption clause to the entire FDCA." *Id.* at 327. Of course, "[i]t did not do so, but instead wrote a pre-emption clause that applies only to medical devices." *Id.* Congress's preemptive intent regarding medical devices – conveyed by the term "requirement" – therefore has no bearing on the implied-preemption analysis for strict-liability claims.

b. More fundamentally, preemption here turns on the content of petitioner's "state tort duties." *PLIVA*, 131 S. Ct. at 2573. Given the absence of an express congressional statement on preemption, defining those "duties" here is not – as in *Riegel* and *Cipollone* – a matter of divining Congress's perception of state law. Instead, the content of state law in this case is determined by the authoritative decisions of New Hampshire's highest court. *See supra* Part I.A.2.

Invalidating New Hampshire law based on *Cipollone*'s and *Riegel*'s generalized understanding of the common law would eviscerate the principle that this Court defers to state courts' interpretations of state law. Preemption cannot arise from an abstract conflict with state law; it requires a conflict between the FDCA and New Hampshire law as it is actually "interpreted and applied" in the case at hand. *Jones v. Rath Packing Co.*, 430 U.S. 519, 526 (1977). Determining whether such a conflict exists demands deference to the sole body with ultimate authority to interpret New Hampshire law. *See Riley*, 553 U.S. at

425-27. Accordingly, whatever this Court has concluded about Congress's intent to preempt common-law actions in express-preemption statutes, it must accept, for purposes of implied impossibility preemption, New Hampshire's conclusion that its product-liability rules impose no substantive "common law . . . duty" on manufacturers. *Bagley*, 503 A.2d at 825.

c. The plurality's statement in *Cipollone*, repeated in *Riegel*, 552 U.S. at 324, that a damages award "'can be, indeed is designed to be, a potent method of governing conduct'" is not to the contrary. 505 U.S. at 521 (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)). That statement, derived from this Court's decision in *Garmon*, was originally premised on a "special presumption of federal pre-emption relating to the primary jurisdiction of the National Labor Relations Board." *Id.* at 537 n.3 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part) (internal quotations omitted). The opposite presumption applies here. *See Levine*, 555 U.S. at 565 & n.3, 575; *see also Lohr*, 518 U.S. at 485 (recognizing "the historic primacy of state regulation of matters of health and safety"). And, whatever the merits of *Garmon*'s understanding of state law in general, it does not accurately describe New Hampshire's strict-liability law. *See LeFavor*, 604 A.2d at 572 (strict liability is not a means of enforcing any "required standard of conduct").

Moreover, even this Court's express-preemption cases have acknowledged relevant differences for preemption purposes between state common law as applied in damages actions and direct regulation. *See Cipollone*, 505 U.S. at 538 (Blackmun, J., concurring in part) (noting "the recognized distinction in

this Court's jurisprudence between direct state regulation and the indirect regulatory effects of common-law damages actions"). As the unanimous Court in *Sprietsma* recognized, "unlike most administrative and legislative regulations," common-law claims "perform an important remedial role in compensating accident victims." 537 U.S. at 64. Even leaving aside the particular features of New Hampshire law, therefore, it is "perfectly rational" to treat common-law claims differently when considering an implied-preemption defense. *Id.*; *see Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988) ("incidental regulatory effects" of tort law differ from the "significantly more intrusive" effects of "direct regulation").

B. The District Court's Judgment Is Not Premised On A Duty To Change Sulindac's Labeling

1. Petitioner forfeited that argument

Although the petition presented the question whether *PLIVA* applies to "design-defect claims," Pet. i, petitioner and the government now contend that *PLIVA* "squarely forecloses" Ms. Bartlett's claim, because the district court's judgment assertedly "reflects a duty to alter" sulindac's "labeling." Pet. Br. 36; U.S. Br. 12.[14]

Petitioner failed to preserve that argument. Petitioner's opening post-trial briefs contained no "warning-related pre-emption argument," and the district court held any such argument "waived." App. 73a; *see also* App. 67a. The First Circuit subsequently re-

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[14] Not until its certiorari reply did petitioner raise the claim – later advanced by the government (at 9-10, 17) – that "the [jury] instructions in this case make clear that the jury's verdict hinged on . . . a finding that petitioner's FDA-mandated warnings were inadequate." Cert. Reply 1, 8.

jected petitioner's attempt to resurrect the argument as a challenge to the jury instructions, because petitioner "failed to seek" an appropriate instruction "before the jury retired." App. 19a.[15] The appellate court thus had no occasion to pass on whether the judgment is preempted because it purportedly rests on a duty to warn. This Court should not address that question in the first instance.[16]

Petitioner's summary-judgment motion did not preserve its warning-related preemption argument. *Cf.* Pet. Br. 22. To preserve an argument that is rejected "at the summary-judgment stage," a litigant must "renew[]" the argument in its post-trial briefing to "avoid surprise" and "to give the district court an opportunity to correct its own mistakes." *Rekhi v. Wildmood Indus., Inc.*, 61 F.3d 1313, 1318 (7th Cir. 1995) (Posner, J.). That principle is particularly important here, because petitioner's warning-preemption argument requires consideration of the actual evidence, argument, and jury instructions given at trial.[17] Petitioner's argument, therefore, does

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[15] Unchallenged jury instructions generally are binding on the parties. This Court has noted a "considerable prudential objection to reversing a judgment because of instructions that petitioner accepted." *City of Springfield v. Kibbe*, 480 U.S. 257, 259 (1987) (per curiam).

[16] *See Adarand Constructors, Inc. v. Mineta*, 534 U.S. 103, 110 (2001) (per curiam) ("this is a court of final review and not first view") (internal quotations omitted); *Davis v. United States*, 495 U.S. 472, 489 (1990) ("Because this argument was neither raised before nor decided by the Court of Appeals, we decline to address it here.").

[17] *Cf. Dunlap v. G&L Holding Group, Inc.*, 381 F.3d 1285, 1297 (11th Cir. 2004) ("any case of federal preemption of state law is highly dependent upon the facts presented and the claims actually pled by the parties") (internal quotations omitted).

not "present neat abstract issues of law," but rather implicates complex fact-bound issues that should have been raised in a "postverdict motion." *Ortiz v. Jordan*, 131 S. Ct. 884, 893 (2011) (internal quotations omitted).

Nor is petitioner's warning theory simply another "argument" supporting its preemption "claim." The courts below did not see it that way, and this Court has rejected the argument that "'statutory preemption' [is] a sufficient claim to give [a petitioner] license" to raise new preemption theories on appeal. *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 486-87 & n.6 (2008).

2. Strict liability in New Hampshire is not premised on a duty to change a product's labeling

Petitioner's and the government's warning theory also fails on the merits. In New Hampshire, "design defect and failure to warn claims are separate." *LeBlanc v. American Honda Motor Co.*, 688 A.2d 556, 562 (N.H. 1997). A strict-liability design-defect claim asks a jury to evaluate a product's overall risks and benefits to determine if it is "unreasonably dangerous." *Id.* In some cases, a jury can consider a warning's potential to lower a product's risks. *See Vautour*, 784 A.2d at 1182. But the basis for liability remains the product's overall dangerousness, not the warning. *See LeBlanc*, 688 A.2d at 562.[18]

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[18] The government erroneously relies (at 16-17) on *Chellman v. Saab-Scania AB*, but that case held only that a plaintiff asserting a design-defect claim was entitled to a jury "instruction on failure to warn" where his pre-trial statement explicitly asserted the defendant's "failure to warn." 637 A.2d at 150-51 (internal quotations omitted). *Chellman* "did not need to or purport to decide whether proving defective warning and prov-

In a strict-liability design-defect case, unlike in a failure-to-warn case, the legal adequacy of a warning is neither a necessary nor a sufficient condition for finding a product unreasonably dangerous. A legally adequate warning does not immunize a manufacturer from liability for selling an unreasonably dangerous product. *Id.* (strict product "'liability may attach even though . . . there was adequate warning'") (quoting *Thibault*, 395 A.2d at 847). Nor does a legally inadequate warning alone establish a design defect; a product whose benefits exceed its risks is not unreasonably dangerous, whatever its warning. *See id.* at 561-62. In either case, the warning is merely one of "many possible factors" that might influence the product's overall dangerousness. *Vautour*, 784 A.2d at 1182.

This Court squarely recognized that distinction in *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). There, the Court explained that a federal statute expressly preempting pesticide "requirements for 'labeling or packaging'" did not preempt design-defect claims because it is "perfectly clear" that common-law "claims for defective design" do not "require[] that manufacturers label or package their products in any particular way." *Id.* at 444. Thus, although federal law might preempt a failure-to-warn claim demanding that a manufacturer improve a "pesticide's label," *id.* at 453, it does not preempt claims alleging that the pesticide's underlying design is unreasonably dangerous.

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ing defective design in respects apart from warning were two separable ways of proving strict product liability." *Cheshire Med. Ctr. v. W.R. Grace & Co.*, 49 F.3d 26, 32 (1st Cir. 1995). *LeBlanc*, decided after *Chellman* and ignored by the government, confirms that strict-liability design-defect claims are not predicated on a failure to warn.

So too here. As with the design-defect claim in *Bates*, the district court's judgment does not require petitioner to "label or package [sulindac] in any particular way." *Id.* at 444. At most, a warning could have influenced the jury's overall assessment of sulindac's risks. The jury's ultimate conclusion that those risks outstripped sulindac's benefits, however, was not equivalent to a command that petitioner improve its warning. The mere possibility that "a finding of liability . . . would induce [petitioner] to alter [its] label" would not be a sufficient basis for preemption. *Id.* at 445 (internal quotations omitted; third alteration in original).[19]

3. The trial record confirms the judgment was not premised on a duty to improve sulindac's labeling

Petitioner's and the government's effort to equate Ms. Bartlett's claim with the failure-to-warn claim at issue in *PLIVA* also disregards the record. Ms. Bart-

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[19] *Kurns v. Railroad Friction Products Corp.*, 132 S. Ct. 1261 (2012), on which petitioner relies (at 34), addressed field preemption, not conflict preemption. There, the Court reasoned that the threat of liability for failure to warn of a danger posed by a locomotive's design "will inevitably influence a manufacturer's choice whether to use that particular design." 132 S. Ct. at 1268 n.4. Because Congress had occupied a "broad" field relating to "the design, the construction and the material" of locomotives, any "influence" on locomotive design sufficed to bring the claim within the preempted field. *Id.* at 1266, 1268 n.4 (internal quotations omitted). Here, however, petitioner must show an *actual* conflict between the district court's judgment and federal regulation of sulindac's label. *Bates* resolved a similar question in the express-preemption context by holding that design-defect claims do not impose labeling requirements that conflict with federal standards. There is no reason to impute a *greater* congressional intent to preempt design-defect claims here than in *Bates*.

lett's complaint asserted discrete counts alleging design defect (JA104-08) and failure to warn (JA102-04), and the parties litigated the two claims separately. The district court awarded petitioner summary judgment on the failure-to-warn claim because no evidence indicated that a stronger warning would have dissuaded Ms. Bartlett's doctor from prescribing sulindac. App. 116a. That conclusion, however, did not affect the separate strict-liability design-defect claim, whose "chain of causation . . . does not run through the warning." App. 68a.

Thereafter, petitioner "voluntarily withdrew" its comment k defense before trial. App. 36a, 60a-61a. With petitioner's "'comment k' defense out of the case, the adequacy of sulindac's warning . . . was no longer an issue for trial." App. 36a. In light of that tactical decision, petitioner's argument (at 35) that "design-defect and failure-to-warn claims . . . collapse together in cases targeting drugs" is mystifying. Petitioner's primary reason for asserting (at 34-35) that such claims "collapse together" is that most States "follow[] comment k." But, whatever implications comment k may have for design-defect claims in general, it assuredly played no role in the judgment here. *See* App. 36a.

Petitioner's tactical decision to withdraw its comment k defense meant that liability could not be premised on petitioner's failure to provide an adequate warning. True, the warning remained a factor in the overall inquiry: the jury was instructed to consider the possible "effectiveness of a warning" in determining sulindac's risks. JA513-14.[20] But that

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[20] Sulindac's warning remained relevant at petitioner's insistence: petitioner was "unwilling to accept" jury instructions that would have "ke[pt] the warning out of the case" by requir-

does not suggest that liability was predicated on a breach of any *duty* to improve the warning. *See* App. 74a. Only the warning's *effect* on sulindac's overall dangerousness remained relevant; its "adequacy" – whether it discharged petitioner's separate common-law duty to warn prescribers about SJS/TEN – was not a subject for the jury's assessment. App. 36a. Thus, "[t]he warning was not sulindac's defective condition; the unreasonable danger was." App. 67a.[21]

Petitioner cannot even show that it would have avoided liability by strengthening sulindac's warning. Ms. Bartlett presented a plethora of evidence that sulindac's risk of causing SJS/TEN swamped its comparative therapeutic benefits, *see supra* pp. 9-10, and she argued that sulindac thus was a "needless and useless drug," 9/2/2010 p.m. Tr. 48:8. By contrast, petitioner put on no affirmative case. App. 30a. Petitioner therefore lacks any evidentiary basis to argue now that sulindac would have been found reasonable with a better warning. In fact, a warning likely would not have made any difference: FDA staff has concluded that "there is no satisfactory method" for "preventing" SJS/TEN, "short of avoiding drugs altogether." JA639 (Lois La Grenade et al., *Comparison of Reporting of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Association*

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ing the jury to analyze sulindac "'as if there were no warning.'" JA345.

[21] Contrary to the government's assertion (at 17), Ms. Bartlett's summation reflected the district court's careful distinction between the warning's legal adequacy and its effect on sulindac's overall risk-benefit profile. Counsel noted that the jury could "consider the presence or efficacy or effectiveness of a warning to avoid unreasonable danger" and explained that sulindac's "label [wa]s ineffective" to avoid its otherwise unreasonable danger of causing SJS/TEN. 9/2/2010 p.m. Tr. 83:2-6.

with Selective COX-2 Inhibitors, 28 Drug Safety 917, 922 (2005)). Petitioner therefore cannot say it was held liable for failing to change sulindac's labeling.

Ultimately, the district judge who actually heard the evidence disagreed unequivocally with the government's post-hoc characterization (at 17) of Ms. Bartlett's claim as a "hybrid design-and-warning" claim. He explained, just before closing arguments, that "I want to avoid any suggestion to this jury that there's a duty to warn on [petitioner's] part because this is not a negligence case or even a products liability case that in some way implicates duty." JA496. As the judge emphasized, "[t]his is not a failure to warn case." *Id.* The district court's informed understanding of Ms. Bartlett's claims, as they were actually litigated, merits this Court's deference. *Cf. Sprint/United Mgmt. Co. v. Mendelsohn*, 552 U.S. 379, 384 (2008) (recognizing need for "deference to a district court's familiarity with the details of [a] case").

C. Even If The Judgment Were Premised On A Duty Not To Sell An Unreasonably Dangerous Product, Compliance With That Duty Would Be Possible

Petitioner and the government argue incorrectly that it would be impossible for petitioner to comply with a duty not to sell sulindac in New Hampshire. As the First Circuit correctly explained, the FDCA allows a manufacturer "not to make the drug at all." App. 10a. And numerous manufacturers have voluntarily withdrawn their drugs from the market without violating any federal mandate.[22] Physical impos-

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[22] Aside from an exception for certain life-saving drugs that is not applicable here, *see* 21 U.S.C. § 356c, the FDCA explicitly

sibility exists only where state and federal law "impose directly conflicting duties," as would be the case if "the federal law said, 'you must sell [sulindac],' while the state law said, 'you may not.'" *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 31 (1996). That is not the case here. *See Michigan Canners & Freezers Ass'n, Inc. v. Agricultural Mktg. & Bargaining Bd.*, 467 U.S. 461, 478 n.21 (1984) (no impossibility where law is "cast in permissive rather than mandatory terms").[23]

Petitioner assails what it calls the First Circuit's "stop-selling rationale" because a manufacturer assertedly can always "avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether." Pet. Br. 43-44 (internal quotations omitted). But if suspending sales *is the state-law duty itself*, then the issue is not whether petitioner could "avoid" state law by suspending sales. Rather, it would be perfectly "lawful under federal law for [petitioner] to do what state law require[s] of

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contemplates that manufacturers will voluntarily discontinue drugs that become unsafe or obsolete. *See id.* §§ 355(j)(6), 360(j)(2)(B), 360bb(b)(1). Ten drugs were voluntarily withdrawn for safety reasons between 2000 and 2006. *See* U.S. Gov't Accountability Office, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process* 10 (Mar. 2006), *available at* http://www.gao.gov/new.items/d06402.pdf; *see also* Wallace F. Janssen, *The Story of the Laws Behind the Labels* (June 1981) ("since 1962 thousands of prescription drugs have been taken off the U.S. market because they lacked evidence of safety and/or effectiveness"), *available at* http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm.

[23] As petitioner's *amicus* recognizes, "the FDCA does not affirmatively *require* [petitioner] to make sulindac or sell it in New Hampshire, so it would not be 'impossible' for [petitioner] to comply with both federal and state law." PLAC Br. 19 n.12.

[it]." *PLIVA*, 131 S. Ct. at 2577; *see* App. 10a (state law can "tell [petitioner] it ought not to [sell sulindac] if risk-benefit analysis weights against the drug").

That modest conclusion has no bearing on the vast majority of impossibility-preemption cases (and no bearing whatsoever on purposes-and-objectives preemption). Where, as in *PLIVA*, state law imposes an affirmative duty on a manufacturer to improve the product's label, suspending sales does not *comply* with the state-law duty; it merely offers an indirect means of avoiding liability for noncompliance with that duty.[24] By contrast, where liability is imposed for selling an unreasonably dangerous product that cannot be improved through a different design or label, a manufacturer's decision to remove its product from the market does not conflict with any federal mandate. If a State's strict-liability law imposes a tort duty on a manufacturer to withdraw an unreasonably dangerous drug from the market, nothing in federal law preempts that decision.

II. THE JUDGMENT POSES NO OBSTACLE TO THE FEDERAL REGIME

Petitioner now devotes an entire section of its merits brief (at 46-62) to arguing that the district court's judgment conflicts with Congress's purposes and objectives. Petitioner failed to raise that issue in its

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[24] *PLIVA*'s facts underscore that distinction. There, the injured patients took metoclopramide "for several years" and alleged that the manufacturers should have warned of the unique risks of "long-term" use. 131 S. Ct. at 2573. The duty alleged thus was not to withdraw metoclopramide from the market, but to instruct prescribers how to use it safely. Given those allegations, it is far from clear the manufacturers could have avoided liability even by suspending sales. *Cf. Hodder v. Goodyear Tire & Rubber Co.*, 426 N.W. 826, 833 (Minn. 1988) (noting that manufacturer's "duty to warn" can "continu[e] post-sale").

certiorari petition, which asserted a conflict with *PLIVA*. *See* Pet. i (asserting conflict with *PLIVA*); *PLIVA*, 131 S. Ct. at 2581 n.7 (noting purposes-and-objectives preemption not argued there); Opp. 21, 28 n.22. The Court should not consider that argument. *See* Sup. Ct. R. 14.1(a); *Beck v. PACE Int'l Union*, 551 U.S. 96, 104 n.3 (2007); *Exxon*, 554 U.S. at 486-87.

In any event, petitioner's new argument lacks merit. Obstacle preemption, like impossibility preemption, has "a high threshold." *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 110 (1992) (Kennedy, J., concurring in part and concurring in the judgment). An impermissible obstacle exists only if state law "impose[s] prohibitions or obligations which are in direct contradiction to Congress' primary objectives, as conveyed with clarity" in federal law. *Id.* Thus, obstacle-preemption analysis is not a "free-wheeling judicial inquiry into whether a state statute is in tension with federal objectives, but an inquiry into whether the ordinary meanings of state and federal law conflict." *Levine*, 555 U.S. at 588 (Thomas, J., concurring in the judgment) (internal quotations omitted). No obstacle exists here.

A. State-Law Claims Like Ms. Bartlett's Complement The FDCA

State damages actions further the FDCA's "high purpose" of "protect[ing] consumers who . . . are largely unable to protect themselves" from dangerous drugs. *Kordel v. United States*, 335 U.S. 345, 349 (1948). They "serve a distinct compensatory function," which "may motivate injured persons to come forward with information" useful to FDA. *Levine*, 555 U.S. at 579.

The incentive that tort law provides for injured patients to make their injuries known provides an

essential supplement to FDA regulation. *See id.* ("[s]tate tort suits uncover unknown drug hazards"); *Bates*, 544 U.S. at 451. The risk-benefit profile of FDA-approved drugs often changes during "the postmarketing phase" as "new risks emerge." *Levine*, 555 U.S. at 579; *see id.* at 569 (noting that "risk information accumulates over time"). As *Levine* recognized, FDA "has limited resources to monitor the 11,000 drugs on the market" and often lacks optimal information about post-approval risks. *Id.* at 578-79.[25] The agency thus depends on manufacturers to "maintain extensive clinical records and make numerous reports to FDA." U.S. Br. 26; *accord Levine*, 555 U.S. at 578-79 (noting manufacturers' "superior access to information about their drugs"). Damages actions – by opening a manufacturer's files to civil discovery and subjecting its assertions to adversarial rigor – facilitate the information-gathering process on which FDA surveillance depends.

This case well illustrates that principle. When FDA first approved sulindac, then-available "clinical studies" revealed "only relatively mild" side effects. JA596 (Park, 142 Arch. Intern. Med at 1292). Only during "postmarketing clinical experience" did "reports beg[i]n to accumulate" detailing the serious risks of SJS/TEN. *Id.* The evidence below highlighted that clinical experience, as experts offered a "litany of specific facts" to support their conclusion that sulindac's risks outweighed its benefits. App. 42a;

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[25] The government insinuates (at 10-11) that there must be conflict preemption because Ms. Bartlett's counsel at trial criticized FDA's post-market surveillance capabilities. But counsel's statements were premised directly on the very same studies on which this Court relied in *Levine*. *Compare* 9/2/2010 p.m. Tr. 78-80 *with Levine*, 555 U.S. at 578 n.11.

see App. 42a-47a (describing trial evidence). Ms. Bartlett unearthed several of those facts in discovery, including critical data contained in the unpublished Pharmacia Report. *See* JA166 (ordering supplemental deposition given "significance of the recently discovered manuscript"). Those data showed that sulindac's adjusted reporting rate of SJS/TEN from 1980-1997 "was the highest of any NSAID" on the market. App. 45a; *see* JA626-34.

That evidence, combined with FDA's own conclusion that no particular NSAID is more effective than any other at relieving muscle pain, *see* JA559, and petitioner's lack of affirmative evidence to the contrary, convinced the jury that sulindac's risk of SJS/TEN outweighed its benefits. The jury's determination that petitioner should remedy Ms. Bartlett's injuries fulfilled New Hampshire law's "distinct compensatory function." *Levine*, 555 U.S. at 579. This lawsuit also "aid[ed] in the exposure of new dangers," *Bates*, 544 U.S. at 451 (internal quotations omitted), by surfacing a critical new document revealing sulindac's high adjusted reporting rate for SJS/TEN.

Reversal thus would thwart the FDCA's core purpose of "bolster[ing] consumer protection against harmful products." *Levine*, 555 U.S. at 574. It also would extinguish "'all means of judicial recourse'" for injured consumers of generic drugs. *Lohr*, 518 U.S. at 487 (plurality) (quoting *Silkwood*, 464 U.S. at 251). As the First Circuit observed, patients like Ms. Bartlett have already "lost [their] warning claim[s] by the mere chance of [their] drug store's selection of a generic." App. 11a. This Court should not presume that Congress silently intended to eliminate their only "remaining avenue of relief." *Id.*; *see Bruesewitz*

v. Wyeth LLC, 131 S. Ct. 1068, 1080 (2011) (Court has "expressed doubt that Congress would quietly preempt product-liability claims without providing a federal substitute").

B. Petitioner's Obstacle-Preemption Arguments Lack Any Statutory Basis

Petitioner argues (at 53-58) that the FDCA's premarket approval provisions immunize manufacturers of FDA-approved drugs from state-law damages actions. But the FDCA's fundamental command is that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug" without first securing FDA approval. 21 U.S.C. § 355(a). That straightforward prohibitory language tasks FDA with ensuring that no manufacturer "market[s] a drug without federal approval," *not* with guaranteeing a manufacturer's "unfettered right, for all time, to market its drug." *Levine*, 555 U.S. at 592 (Thomas, J., concurring in the judgment).

Congress knows how to "explicitly grant[]" an entity "authorization, permission, or power" to engage in some activity; it typically does so by providing that an entity "may" engage in that activity. *Barnett Bank*, 517 U.S. at 34-35; *see id.* at 33 (collecting statutes conferring such authorization). Congress's failure to include similar language in the FDCA demonstrates it did not intend FDA approval to confer on manufacturers an affirmative right to market drugs free of common-law liability. Petitioner's repeated references (at 28, 40, 43) to a supposed "right to engage in interstate commerce" thus fundamentally mischaracterize the governing statute.

Levine reinforces that conclusion. There, Wyeth argued that "the FDCA establishes both a floor and a ceiling for drug regulation" and that Ms. Levine's

damages action "interfere[d]" with FDA's efforts to "strike a balance between competing objectives." 555 U.S. at 573 (internal quotations omitted). The Court rejected those arguments because "all evidence of Congress' purposes is to the contrary." *Id.* at 574. It explained that Congress's apparent determination "that widely available state rights of action provided appropriate relief for injured consumers," and its decision not to "enact[] an express pre-emption provision at [any] point during the FDCA's 70-year history," were "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety." *Id.* at 574-75.

Levine's holding that the FDCA embodies no congressional purpose to preempt damages judgments in failure-to-warn cases applies equally to the district court's judgment here.[26] Petitioner fails to identify any statutory language not before the Court in *Levine*. Instead, it relies (at 54, 58) on FDA's authority to approve (and withdraw approval of) an application to market a drug. But Congress intended that authority to offer consumers "protection *against* harmful products" – not to subsidize the distribution of products that FDA deems safe. *Levine*, 555 U.S. at 574 (emphasis added); *see United States v. Dotterweich*, 320 U.S. 277, 280 (1943) (FDCA's core purpose is "to keep impure and adulterated food and

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[26] The government maintains (at 33) that the *Levine* Court's conclusion is inapplicable because the Court cited Justice Ginsburg's dissent in *Riegel*. The government asserts that the cases Justice Ginsburg cited (despite her statement to the contrary) "primarily involved failure-to-warn claims." *See Riegel*, 552 U.S. at 340 (Ginsberg, J., dissenting) (discussing "claims for drug labeling *and design defects*") (emphasis added). But for decades courts have considered design-defect claims independent of any free-standing duty to warn. *See supra* note 3.

drugs out of the channels of commerce").[27] Nothing about the district court's judgment affects – much less undermines – FDA's ability to perform its gatekeeping function.

Moreover, petitioner is mistaken (at 56) that the statute evinces an intent to prohibit "lay juries" from evaluating drug safety. The jury's determination that sulindac was unreasonably dangerous directly parallels the FDCA's misbranding provision, which provides that a drug is "misbranded" – and therefore cannot be sold in interstate commerce, *see* 21 U.S.C. § 331 – if it is "dangerous to health" when used as provided in the labeling. *Id.* § 352(j). The FDCA "contemplates that federal *juries* will resolve most misbranding claims," *Levine*, 555 U.S. at 570 (emphasis added), and FDA's "belief that a drug is misbranded is not conclusive," *id.* Thus, Congress did not intend to preclude juries wholesale from determining whether drugs are unreasonably "dangerous to health" in light of their labeling, 21 U.S.C. § 352(j). *See Bates*, 544 U.S. at 452 (rejecting preemption argument based on mistrust of juries because, in prosecutions under federal pesticide law, "juries necessarily pass on allegations of misbranding").[28]

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[27] The "statutory protections" cited by petitioner (at 54) confirm FDA's gatekeeper role: those protections apply to FDA's authority to "withdraw," "suspend," or "refus[e]" approval of a drug application. 21 U.S.C. § 355(e), (h). None suggests FDA authority affirmatively to promote drug sales.

[28] Petitioner also asserts (at 58) that the district court's judgment "strips" it of the "protections federal law grants [it] before [its] products lawfully can be ordered withdrawn from interstate commerce." But the judgment does not "order[]" petitioner to "withdraw[]" sulindac from interstate commerce; it simply requires petitioner to pay damages. *See supra* pp. 18-22.

C. The Government's Assertion That The District Court's Judgment Impedes FDA Regulation Is Unpersuasive

The government acknowledges (at 21) that "[s]everal factors do weigh" *against* finding design-defect claims preempted. Chief among those factors, which the government regards as "significant," is *Levine*'s holding that many "state-law tort actions have long been understood to complement FDA drug-safety regulation." *Id.* at 22.

Nonetheless, despite calling (at 12) the issue "difficult and close," the government concludes that Ms. Bartlett's claim conflicts with federal law because it assertedly allowed a jury to "second-guess FDA's safety determination" and thereby undermined the "assurance that FDA's approval provides" to drug manufacturers. *Id.* at 28 (internal quotations and brackets omitted). That asserted conflict, as the government essentially concedes, lacks any grounding in the statute. *See id.* at 21 (acknowledging nothing in FDCA requires a "manufacturer be guaranteed the ability" to sell an approved drug "in any particular State"); *supra* pp. 43-45. It also conflicts with FDA's previous positions, depends on unfounded assumptions about the effect of the district court's judgment, and misstates the record in this case.

Regardless, petitioner cross-examined Ms. Bartlett's witnesses, had an opportunity (and opted not) to put on its own witnesses and evidence, and received searching review of the verdict from both courts below. Petitioner, therefore, has received no shortage of process.

1. The government's brief deserves no weight because it lacks any basis in lawful regulations and conflicts with FDA's prior positions

This Court does "not defer to an agency's ultimate conclusion about whether state law should be pre-empted." *PLIVA*, 131 S. Ct. at 2575 n.3. The government's assertion that Ms. Bartlett's claim interferes with federal objectives is particularly unpersuasive because FDA has never "embod[ied] [that] determination[] in lawful specific regulations." *Levine*, 555 U.S. at 582 (Breyer, J., concurring). The pertinent regulations – like the FDCA's text – demonstrate that FDA approval merely allows a drug into interstate commerce. *See* 21 C.F.R. § 314.105(a) ("A new drug product . . . may not be marketed until an approval is effective."). FDA's approval decision reflects the agency's judgment that an approved drug "meets the statutory standards" – not that it must (or even should) be sold in any particular State. *Id.* § 314.105(c).

The government asserts that FDA approval has preemptive effect because it reflects the agency's determination that a "drug's likely 'therapeutic benefits . . . outweigh its risk of harm.'" U.S. Br. 24 (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000)) (alteration in original). In *Brown & Williamson*, however, this Court held that FDA's gatekeeper role does not give it authority to promote "public health" in general. 529 U.S. at 139-40 (FDA charged with making only the "specific safety determinations required by the FDCA[]") (internal quotations omitted). Indeed, FDA merely decides whether the FDCA bars a drug from interstate commerce; the medical "consequences of not permitting [a] product

to be marketed" are beyond FDA's purview. *Id.* at 139 (internal quotations omitted).

This case is thus quite unlike *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), on which both petitioner (at 50) and the government (at 28-29) rely. There, the Court found that a suit premised on an automaker's failure to install airbags conflicted with a binding regulation that "deliberately" sought "a mix of several different passive restraint systems." 529 U.S. at 878-79. As this Court later clarified, *Geier* reached that conclusion because the agency had "conducted a formal rulemaking" and embodied its decision to promote manufacturer flexibility in a "specific agency regulation bearing the force of law." *Levine*, 555 U.S. at 580. Like *Levine*, this case involves "no such regulation," but rather turns on FDA's "mere assertion that state law is an obstacle to achieving its statutory objectives." *Id.* at 576. The consideration to be given FDA's position therefore depends on its "thoroughness, consistency, and persuasiveness." *Id.* at 577.

Under that standard, the government's position deserves no weight. Indeed, FDA's position in recent years concerning the FDCA's preemption of state-law actions against drug manufacturers has been decidedly schizophrenic. For years, FDA endorsed the general premise that "product liability plays an important role in consumer protection." 59 Fed. Reg. 3944, 3948 (1994); *see* 63 Fed. Reg. 66,378, 66,384 (1998) ("FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations."). In 2006, FDA abruptly changed views and inserted language in a regulatory preamble propounding the same argument advanced here: that

"[s]tate law actions . . . threaten FDA's statutorily prescribed role as the expert Federal agency" by allowing "lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public." 71 Fed. Reg. 3922, 3935 (2006).

In *Levine*, this Court gave no weight to the preamble because FDA had reversed its "own longstanding position without providing a reasoned explanation." 555 U.S. at 577. Two years later, FDA explained that, in view of *Levine*, it had concluded that "the position on preemption articulated in the preamble . . . cannot be justified under legal principles governing preemption." 76 Fed. Reg. 61,565, 61,565 (2011). It therefore withdrew the entire preamble, including its excursus on the dangers of "lay" juries "second-guess[ing]" FDA's "assessment of benefits versus risks of a specific drug," 71 Fed. Reg. at 3935; *see* 76 Fed. Reg. at 61,565 (noting that preamble had "discussed [FDA's] views on the preemptive effect of both the [attached labeling] regulation[]" and, "more generally, the [FDCA]").

FDA's present attempt to change position *yet again* – without citing even a non-binding preamble in support – is utterly unpersuasive. Not only has the government abandoned its previous view, but it has again formulated its litigating position without providing the "notice or opportunity for comment" essential to a thorough consideration of whether strict-liability claims actually impede federal regulation. *Levine*, 555 U.S. at 577. Accordingly, the government's brief "does not merit deference." *Id.*

2. The government makes baseless assumptions about the effects of the district court's judgment

The government's position also rests on a faulty premise. The government asserts that a damages judgment "would undermine the federal regime *to the extent that* [it] forb[i]d[s] or significantly restrict[s] the marketing of an FDA-approved drug." U.S. Br. 13 (emphasis added). Its preemption position thus depends on the premise that the district court's judgment will force petitioner to "abandon" the market, "cause" the "withdrawal" of sulindac from interstate commerce, "materially increase [sulindac's] price," or "depriv[e] individuals of access to" sulindac. *Id.* at 27-29.

Those assertions are unfounded. Although drug manufacturers have been subject to design-defect liability for decades, *see supra* pp. 3-4, the government identifies no evidence that manufacturers have stopped selling drugs or materially increased their prices in response to state-law damages judgments. *See Bates*, 544 U.S. at 451-52 (rejecting government argument that "exaggerate[d] the disruptive effects of . . . common-law suits" and cited "no evidence" that "tort suits . . . created any real hardship for manufacturers").

Nor is there any evidence that affirming the judgment will have those effects. The jury was permitted to award only compensatory damages, and the record contains no evidence that those damages are sufficiently large to dissuade petitioner (or other manufacturers) from selling sulindac in New Hampshire. *Cf. Silkwood*, 464 U.S. at 258 n.18 (noting lack of "evidence" that damages would "put a licensee out of business" and thus "conflict with [federal] policy"

concerning nuclear safety) (internal quotations omitted).

It is similarly unlikely that the threat of liability in future cases would cause sulindac manufacturers to abandon the market or materially raise their prices. According to petitioner (at 19), "SJS/TEN is exceptionally rare." And the next case (if there is one) could well come out very differently. Petitioner's unorthodox litigating tactics were pivotal to the outcome of this case: petitioner "'engineered' a broader scope of liability by voluntarily withdrawing" its comment k defense "on the eve of trial." App. 60a. Other manufacturers (and presumably petitioner itself) would likely not repeat the same tactic.[29]

3. The government's position mischaracterizes the record

The government's obstacle-preemption argument also fails because the jury verdict in this case did not "second-guess" any "expert determination" by FDA. U.S. Br. 29. Sulindac's risks were not fully apparent when FDA first approved Clinoril in 1978. *See supra* p. 5. Indeed, when Ms. Bartlett's doctor prescribed Clinoril in December 2004, the information contained in Clinoril's NDA was decades out of date. The government does not contend that FDA, at that critical

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[29] The judgment would have no issue-preclusive effect in a subsequent suit against petitioner. In general, "[d]ispersed mass torts" have spurred "great[] distrust of nonmutual preclusion." 18A Charles A. Wright et al., *Federal Practice and Procedure* § 4465.3, at 783 (2d ed. 2002). Moreover, whatever the theoretical possibility of non-mutual issue preclusion, petitioner's decision to waive its comment k defense would negate such preclusion here. *See Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 330 (1979) (calling non-mutual estoppel "unfair" where defendant declines "to defend vigorously" on key issues in first action).

juncture, had analyzed whether its then-decades-old approval of Clinoril's NDA remained justified.

Rather, the government relies on the fact that, after FDA conducted its 2005 review of cardiovascular risks in NSAIDs – i.e., months *after* Ms. Bartlett's 100-day hospital stay began – the agency "did not conclude that sulindac . . . should be withdrawn from the market." U.S. Br. 30 (internal quotations omitted). FDA's failure to so conclude does not conflict in any way with the district court's judgment. First, FDA did not have all the information that was before the jury. Ms. Bartlett's case at trial rested in significant part on the unpublished Pharmacia Report depicting sulindac's adjusted reporting rate for SJS-TEN. *See supra* p. 10.[30] As the district court explained, the "testimony in the case" indicated that the Report's author "had not turned [it] over to the FDA," and the "evidence is that the FDA did not have it." 9/2/2010 p.m. Tr. 108:3-9. Notwithstanding the government's inexplicable, naked assertion (at 30) to the contrary, it identifies not a shred of evidence – in the trial record or elsewhere – to contradict that undisputed testimony.[31]

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[30] *See also, e.g.*, 9/2/2010 p.m. Tr. 56:11-18 (summation arguing that "FDA . . . cannot take action based upon information they don't have" and that petitioner's expert "never gave [his] report to the FDA").

[31] The government asserts vaguely (at 30) that FDA "had considered the relevant publication addressing spontaneous reporting rates." But the portions of the record the government cites show only that FDA received a *subsequent*, significantly abridged version of the Pharmacia Report. JA297-98, 364. That version contained the raw number of SJS/TEN reports attributed to sulindac; it omitted sulindac's more probative exact reporting *rate* – controlled for number of prescriptions – that Ms. Bartlett utilized at trial. C.A. App. 2368-73.

Moreover, even if FDA was aware of the Pharmacia Report, there is certainly no evidence that FDA actually considered it. FDA recommended that Bextra be withdrawn from the market because the "reporting rate" of serious skin reactions "appear[ed] to be greater for Bextra" than for certain other (non-sulindac) NSAIDs. JA589. In doing so, FDA never acknowledged, much less grappled with, the Pharmacia Report's conclusion that sulindac's SJS/TEN reporting rate from 1980-1997 "was the highest of any NSAID," App. 45a, or the data indicating that sulindac's "risk/benefit profile" was similar to Bextra's, App. 46a-47a; *see* JA477-85. In fact, neither the 2005 staff memorandum nor the 2006 FDA letter responding to the Citizen Petition even mentioned sulindac.

The record, in short, does not substantiate FDA's assertion that it performed a "comprehensive review" of sulindac's risks and benefits. 2006 Letter at 2. If FDA did perform such a review, it neither documented its decisionmaking process nor bothered to respond to the evidence on which Ms. Bartlett's experts based their conclusions. In such circumstances, the mere absence of agency action carries no weight. *See Levine*, 555 U.S. at 580 (finding no preemption where agency's "contemporaneous record" did not "reveal[] the factors the agency had weighed and the balance it had struck"); *see also Altria Group, Inc. v. Good*, 555 U.S. 70, 89-90 (2008) ("agency nonenforcement of a federal statute is not the same as a policy of approval").

In any event, even assuming FDA "considered the relevant publication" on which Ms. Bartlett relied, U.S. Br. 30, FDA's actions still would not demonstrate any conflict with the district court's judgment.

FDA determined after Ms. Bartlett's injuries that "revisions to labeling" for all NSAIDs were "necessary to make more explicit the risks associated with SJS and TEN." 2006 Letter at 7. When Ms. Bartlett took sulindac, the then-effective label lacked such warnings. JA553-54. As such, the jury's conclusion that sulindac *as labeled in 2004* was unreasonably dangerous did not "second-guess" FDA's expert judgment, because FDA had never opined on whether *that* version of sulindac had benefits that outweighed its risks. *See Lohr*, 518 U.S. at 501 (distinguishing case in which "the Federal Government has . . . reached an unambiguous conclusion about how [the relevant] considerations should be resolved in a particular case").[32]

D. The Hatch-Waxman Act Does Not Immunize Generic Drug Manufacturers From Tort Liability

Petitioner additionally contends (at 46-53) that the district court's judgment conflicts with the Hatch-Waxman Act. But that Act, like the FDCA more broadly, evinces no intent to preempt state-law tort actions. Hatch-Waxman was Congress's response to a specific problem: the burden imposed by the "unnecessary and wasteful" requirement that generic

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[32] Nor did the jury's conclusion turn on its ignorance of the "'patients who reaped [the] benefits'" of sulindac. Pet. Br. 56 (quoting *Riegel*, 552 U.S. at 325). The district court instructed the jury to "consider the usefulness and desirability of [sulindac] to the public as a whole." JA513. Thus, Ms. Bartlett's summation focused on the voluminous evidence showing that sulindac provides no benefit relative to other NSAIDs sufficient to justify its heightened reporting rate of SJS/TEN. 9/2/2010 p.m. Tr. 64-66. Petitioner's failure to rebut that evidence reflects not a flaw in the civil jury system, but its own "tactical decision[]" to forgo any affirmative case. App. 30a-31a.

manufacturers replicate a branded drug's regimen of "clinical trials." H.R. Rep. No. 98-857, pt. 1, at 16. Congress thus created the streamlined ANDA process, which was "designed to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).[33]

In so doing, Congress did not bestow on manufacturers a right to market generic drugs free from tort liability. Congress was presumably no less "aware[] of the prevalence of state tort litigation" when it enacted Hatch-Waxman than when it enacted the FDCA, yet it declined – as in the FDCA – to enact an express-preemption clause. *Levine*, 555 U.S. at 575. That is "powerful evidence" Congress "did not intend FDA oversight" of generic drugs to preempt common-law remedies. *Id.*

Petitioner's attempt to read into Hatch-Waxman a broader preemptive purpose is unpersuasive. Petitioner argues (at 52) Congress must have intended to preempt design-defect actions against generic-drug manufacturers because Congress's goal was to "encourage[] the sale of [generic drugs] in interstate commerce." But Hatch-Waxman did not aim to maximize the sale of generic drugs in all circumstances at

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[33] Hatch-Waxman also awards to certain generic-drug applicants a 180-day exclusivity period in which no other ANDAs will be approved. § 101, 98 Stat. 1589. As with the provisions streamlining the ANDA process, the exclusivity period does not evince Congress's intent to maximize generic-drug sales at all costs; it instead represents a measured attempt "to compensate [generic] manufacturers for research and development costs as well as the risk of litigation from patent holders." *Teva Pharm. USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008).

all costs.[34] Congress had a narrower purpose: "to make available *more* low cost generic drugs *by* establishing a generic drug approval procedure." H.R. Rep. No. 98-857, pt. 1, at 14 (emphases added). The common-law requirement that manufacturers compensate injured consumers is "no more a threat" to that narrow purpose than are requirements that generic drug manufacturers "comply with local fire prevention regulations and zoning codes." *Lohr*, 518 U.S. at 501-02.

Ultimately, petitioner views Hatch-Waxman as silently "preclud[ing] state courts from affording state consumers any protection from injuries resulting from a defective [generic drug]." *Id.* at 487 (plurality). That view not only lacks support in Hatch-Waxman itself, but conflicts with the "'statutory framework' surrounding it." *Id.* at 486 (majority) (quoting *Gade*, 505 U.S. at 111 (Kennedy, J., concurring in part and concurring in the judgment)). Hatch-Waxman, after all, forms part of the broader FDCA regulatory regime, which Congress intended "to bolster consumer protection against harmful products." *Levine*, 555 U.S. at 574. Immunizing generic-drug manufacturers from product-liability claims would vitiate that broader regime.

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[34] *See Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987) (per curiam) ("[N]o legislation pursues its purposes at all costs[,] . . . and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law."); *cf. Sprietsma*, 537 U.S. at 70 (although one "goal[]" of the Federal Boat Safety Act of 1971 is "fostering uniformity," that "interest is not unyielding" and cannot "justify the displacement of state common-law remedies . . . that serve the Act's more prominent objective . . . of promoting boating safety").

III. EVEN UNDER THE GOVERNMENT'S "MISBRANDING" THEORY, THE JUDGMENT SHOULD BE AFFIRMED

This Court also should affirm because the drug that petitioner marketed to Ms. Bartlett was misbranded under federal law. The government concedes (at 23) the FDCA does not preempt state-law duties "not to market" drugs in circumstances that "parallel the FDCA's drug 'misbranding' prohibition." The district court's judgment – to the extent it requires anything other than the payment of damages – fits that description. *See supra* p. 45.[35]

The record refutes the government's contention (at 21) that the jury verdict was not "based on new and scientifically significant information." Not only did FDA never consider the Pharmacia Report on which Ms. Bartlett relied, *see supra* pp. 52-53, but FDA only reexamined NSAIDs *after* Ms. Bartlett had taken sulindac, *see* JA580 n.8. And FDA's subsequent determination that sulindac should bear a strengthened warning suggests, if anything, that sulindac *as sold to Ms. Bartlett* was, in FDA's view, "'dangerous to health' when used as provided in the labeling." U.S. Br. 23 (quoting 21 U.S.C. § 352(j)).

Because the jury reasonably could have concluded that sulindac was misbranded under federal law, this Court should affirm. Alternatively, it should (at most) remand so that Ms. Bartlett is afforded an op-

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[35] Petitioner did not preserve a challenge to the sufficiency of the evidence based on the government's misbranding theory. *See Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394 (2006). Nor did it preserve an argument that the instructions should have required the jury expressly to find that the verdict was based on "new" evidence. *See* Fed. R. Civ. P. 51(d)(1).

portunity to prove her case under the government's newly minted standard, which petitioner never raised below. *See Bates*, 544 U.S. at 453 & n.27.

CONCLUSION

The judgment of the court of appeals should be affirmed or, in the alternative, remanded for retrial on misbranding.

Respectfully submitted,

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February 13, 2013

REPLY BRIEF

No. 12-142

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

REPLY BRIEF OF PETITIONER MUTUAL PHARMACEUTICAL COMPANY, INC.

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March 12, 2013

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rules 24.1(b) and 29.6, Petitioner Mutual Pharmaceutical Company, Inc. ("Mutual") is a wholly owned subsidiary of URL Pharma, Inc. URL Pharma, Inc. is a wholly owned subsidiary of Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"). Caraco's shares are owned in part by Sun Pharmaceutical Industries, Ltd. ("Sun Limited"), and in part by Sun Pharma Global, Inc. Sun Pharma Global, Inc. is wholly owned by Sun Limited. Shares of Sun Limited are traded on both the National Stock Exchange and the Bombay Stock Exchange in India. No other publicly held corporation owns 10 percent or more of Mutual's stock.

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INTRODUCTION

Respondent does not dispute that the federal sameness mandate *Mensing* found dispositive applies equally to generic warnings and generic design. And she essentially abandons the First Circuit's stop-selling theory, which only highlights the direct conflict between state and federal law. Instead, she tries to distinguish *Mensing* on the curious ground that it involved only "negligence-based failure-to-warn claims," Red Br. 1, whereas her strict-liability claim "is not premised on any underlying standard" because it only requires "paying compensatory damages." *Id.*

That distinction is wrong at every turn. As a factual matter, *Mensing* involved both negligence-based and strict liability failure-to-warn claims—as the *Mensing* plaintiffs themselves told this Court. As a constitutional matter, this Court's preemption jurisprudence has *never* distinguished between negligence and strict-liability claims that conflict with federal standards. Instead, the Court's cases repeatedly have found *both* kinds of claims preempted, because the Supremacy Clause prohibits enforcement of any state-law standard that federal law bars a regulated party from satisfying.

Finally, respondent's distinction has no basis in state law, which does not remotely establish the standardless liability scheme respondent imagines. Instead, the New Hampshire Supreme Court has made clear that strict liability does "*not* ... impose absolute liability on manufacturers or make them insurers of their products." *Price v. BIC Corp.*, 702

A.2d 330, 333 (1997).[1] Under well-settled law, design-defect plaintiffs injured by a prescription drug thus can recover damages *only if* a jury concludes the drug's benefits outweighed its risks *and* that its warnings were insufficient. No less than in *Mensing*, Hatch-Waxman's sameness mandate bars generic companies from satisfying this state-law standard. The judgment should be reversed.

ARGUMENT

I. Respondent's Design-Defect Claim Directly Conflicts With Federal Law.

Respondent's basic argument is that the Supremacy Clause categorically distinguishes between strict-liability and negligence claims for preemption purposes. Red Br. 18-30. But that distinction is drawn from whole cloth. This Court long ago made clear that federal preemption depends not on whether state law is grounded in negligence or strict liability, but instead on the substantive standard it seeks to enforce: At its core, the Supremacy Clause bars states from enforcing any standard that federal law precludes a regulated party from satisfying. *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985); *AT&T Co. v. Cent. Office Tel., Inc.*, 524 U.S. 214, 221-26 (1998); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

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[1] All emphases added unless otherwise noted.

A. The Supremacy Clause Does Not Distinguish Between Negligence And Strict-Liability Claims.

Respondent's principal contention is that the Supremacy Clause preempts state-law claims that enforce a fault-based "duty of care" but not those that impose liability "absent traditional legal fault." *Id.* 20 (quotations omitted). She then claims that distinguishes *Mensing*, which allegedly involved only "negligence claims." *Id.* 24; *id.* 1, 14. Not so.

Factually speaking, it is demonstrably false that *Mensing* involved only negligence claims. As Mutual previously noted with record citations, the *Mensing* complaints included *strict liability* failure-to-warn claims. Blue Br. 14. Respondent never even acknowledges this fact. Instead, she suggests this Court must have *assumed* the plaintiffs' claims sounded only in negligence because that allegedly is how the parties described the claims. Red Br. 25. But the *Mensing* plaintiffs expressly noted their claims sounded in both strict liability and negligence. Br. for Resps. 42, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) ("The principal causes of action asserted by both Ms. Mensing and Ms. Demahy in these cases are traditional products liability claims for inadequate warnings. JA106-13 (strict liability); 115-21 (negligence); 143-45 (implied warranty); JA442-45 (La. Prods. Liab. Act)."). It is unlikely that this Court ignored both the record and the plaintiffs' explicit invocation of their strict-liability claims when it held without qualification that "federal law pre-empts *these lawsuits*." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011).

Facts aside, respondent's theory of preemption is untenable. The Supremacy Clause's plain terms do not distinguish between categories of tort claims for preemption purposes; they instead make federal law "the supreme Law of the Land ... *any Thing* in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI cl. 2. It would strain credulity to suggest "the People" understood those broad, unqualified terms as drawing fine distinctions between particular theories of liability when assessing federal law's primacy. *See* S. Johnson, DICTIONARY OF THE ENG. LANGUAGE 2047 (1st ed. 1755) (primary definition of *thing*: "Whatever is; not a person. A general word."); *id.* 141 (primary definition of *any*: "Every; whoever he be; whatever it be. It is, in all its senses, applied *indifferently* to persons or things."). Indeed, the term "thing" historically referenced "[a] matter brought before a court of law; a legal process; a charge brought, a suit or cause pleaded before a court." 11 OXFORD ENG. DICTIONARY 308 (1st ed. reprinted 1970). In that sense, the Constitution's unqualified reference to "any Thing" included *all* legal claims.

Not surprisingly, respondent identifies *no case* where this Court has embraced her newly minted distinction between negligence and strict-liability claims for preemption purposes. Indeed, it is bizarre to think that when state law sanctions a party for violating a standard which federal law barred that party from satisfying, the supremacy of federal law hinges on whether the state deems the party's actions *unreasonable* (preempted) or imposes liability even if the party's actions were *reasonable* (not preempted). A state's moral assessment of "the blameworthiness of the tortfeasor," Torts Profs.' Br.

5, has no logical relevance to federal law's primacy; what matters is whether federal law allowed the regulated party to satisfy the state-law standard being enforced. *Mensing*, 131 S. Ct. at 2579.

That explains why this Court repeatedly has found both negligence and strict-liability claims preempted. *See, e.g.*, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 509 (1992) (complaint "rel[ied] on theories of strict liability, negligence, express warranty, and intentional tort"); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008) (complaint included "claims of strict liability; breach of implied warranty; and negligence"). In either situation, state tort law enforces legal "requirements":

> In *Lohr*, five Justices concluded that common-law causes of action for negligence *and* strict liability do impose "requirements" and would be pre-empted.... We adhere to that view. In interpreting two other statutes we have likewise held that a provision pre-empting state "requirements" pre-empted common-law duties.

Riegel, 552 U.S. at 323-24 (original alteration omitted; citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 512 (1996) (plurality); *id.* at 503-05 (Breyer, J., concurring); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005)).

Given the Court's express recognition that these cases involved negligence *and* strict-liability claims, its references to "duties" in these cases (as well as *Mensing*) could not possibly have been *negligence-specific*. Instead, the cases themselves make clear the term "duty" referenced any claim that enforces a state-law standard, including strict liability. *Riegel*,

552 U.S. at 325 ("[E]xcluding common-law *duties* from the scope of pre-emption would make little sense. State tort law that *requires* a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, *applied by juries under a negligence or strict-liability standard*, is less deserving of preservation.").

Respondent tries to distinguish these cases because they involved express preemption clauses. Red Br. 27-28. But that is irrelevant. Absent contrary indication (like a savings clause), state-law "requirements" which directly conflict with federal law are impliedly preempted. *Mensing*, 131 S. Ct. at 2577 n.5; *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 869 (2000); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995).

What matters, then, is this Court's longstanding recognition that "common-law causes of action for negligence *and* strict liability do impose 'requirements'" within the "normal meaning" of that term. *Riegel*, 552 U.S. at 323-24 (original alteration omitted). Respondent's assertion that strict-liability claims do not "require" anything beyond paying damages and thus *cannot* conflict with federal law is an assault on these decisions. And her suggestion that strict liability might impose "requirements" for purposes of express *but not* implied preemption, Red Br. 27-28, would mean express preemption clauses are *necessary* to preempt common-law claims, which *Mensing* itself refutes. 131 S. Ct. at 2577 n.5.

Indeed, this Court previously has found strict-liability claims impliedly preempted. *International*

Paper Co. v. Ouellette held that federal law preempts strict-liability nuisance claims, and in fact rejected the government's suggestion that such claims might survive preemption because "compensatory damages actions ... only require the source to pay for the external costs created by the pollution, and thus do not 'regulate' in a way inconsistent with [federal law]." 479 U.S. 481, 498 n.19 (1987). And this Court elsewhere has found implied preemption where state law imposes no "duty" other than satisfying state standards or avoiding state proscriptions. *Plains Commerce Bank v. Long Family Land & Cattle Co.*, 554 U.S. 316 (2008) (preempting tribal tort law that limited land sales); *Chamber of Commerce of U.S. v. Brown*, 554 U.S. 60 (2008) (preempting state ban on using state funds to support or oppose unions); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992) (plurality) (preempting state standards for hazardous waste workers); *Douglas v. Seacoast Prods., Inc.*, 431 U.S. 265 (1977) (pre-empting state limits on noncitizen fishing rights); *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236 (1959) (preempting state claim that barred union picketing). Each of these cases was wrongly decided under respondent's approach.[2]

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[2] As for respondent's assertion that common-law claims somehow are less susceptible to preemption than positive law, Red Br. 29-30, this Court has said the opposite: "[T]ort law, applied by juries under a negligence or strict-liability standard, is *less* deserving of preservation" than "state regulatory law." *Riegel*, 552 U.S. at 325; *Lohr*, 518 U.S. at 504 (Breyer, J., concurring). Respondent's contrary suggestion cites only Justice Blackmun's partial *dissent* in *Cipollone* and cases interpreting savings clauses that *explicitly preserved* state

B. New Hampshire's Design-Defect Standard Directly Conflicts With Hatch-Waxman's Sameness Requirement.

This Court's decision in *Mensing* compels reversal. Just as in *Mensing*, Hatch-Waxman's sameness requirement made it *impossible* for Mutual to satisfy New Hampshire's design-defect standard, because it forbade Mutual from altering generic sulindac's risk-benefit profile—whether by modifying the drug's active ingredient or altering its warnings. *Mensing*, 131 S. Ct. at 2574 n.2, 2575 (holding that generic drugs must be "identical [to their branded equivalents] in active ingredients, safety, and efficacy" as well as "warning[s]").

The First Circuit tried to evade this conceded problem with the stop-selling theory. PA10a-11a. But respondent barely defends that theory here, and then only as an afterthought. Red Br. 37-39. Instead, she makes the astonishing claim that "strict liability is not premised on *any* underlying standard" except "to compensate consumers." *Id.* i; *id.* 18-24.

That claim is manifestly incorrect. As respondent elsewhere concedes, New Hampshire's design-defect tort does *not* permit the vast majority of injured

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common-law claims, and which thus are irrelevant here. Red Br. 29-30 (citing *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63-64 (2002) (finding it "rational" for Congress to provide that satisfying federal regulations "does not relieve a person from liability at common law") (quotation omitted); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 186 (1988) (construing savings clause and stating "Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not")).

consumers to recover damages. Instead, damages are available *only if* the injured party can prove the drug was "unreasonably dangerous" because its "risks outweigh its benefits," Red Br. 1; *id.* 21 ("[Strict] liability *turns on whether a product is 'unreasonably dangerous' under [the] 'risk-utility balancing test.'*") (quoting *Price*, 702 A.2d at 332), and that test necessarily requires consideration of both the drug's FDA-mandated active ingredient and its FDA-mandated warnings. PA18a ("[T]he lack of a clearer warning made the product itself more dangerous under [New Hampshire's] risk-benefit test.") (citing *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001)).

That is why the New Hampshire Supreme Court has held that strict liability does "*not* ... impose absolute liability on manufacturers or make them insurers of their products." *Price*, 702 A.2d at 333; *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 845-46 (N.H. 1978) ("[S]trict liability is *not* a no-fault system of compensation."). Again, as respondent's own state-law discussion shows, design-defect liability in New Hampshire necessarily hinges on application of a legal standard—one its Supreme Court calls a safety-based design "duty." *Chellman v. Saab-Scania AB*, 637 A.2d 148, 150 (N.H. 1993) ("The duty to warn is part of the general *duty to design, manufacture and sell products that are reasonably safe* for their foreseeable uses.") (citing *Thibault*, 395 A.2d at 847 (describing "manufacturer's *duty to design his product reasonably safely* for the uses which he can foresee")).

In this case, it was *impossible* for Mutual to satisfy New Hampshire's design standard without

violating federal law. State law required the jury to find that sulindac's "risks outweigh its benefits," Red Br. 1; JA539, and respondent herself concedes that inquiry necessarily required consideration of *both* the drug's inherent risks *and* the FDA-mandated "warning's potential to lower [those] risks." Red Br. 32 (citing *Vautour*, 784 A.2d at 1182). Hatch-Waxman's sameness mandate, however, barred Mutual from changing sulindac's FDA-mandated risk-benefit profile, whether by altering the molecule itself or the warnings. U.S. Br. 15 ("[P]etitioner could *not* make changes that created a different active ingredient or strengthened the warning."). That made it impossible for Mutual to comply with New Hampshire's design standard without violating federal law, foreclosing liability as a matter of law.

Mensing is directly on point. Its *rationale* controls, because Mutual had no more power to alter the sulindac molecule than the *Mensing* defendants had to alter the warnings. And *Mensing*'s *holding* controls, because New Hampshire law impermissibly conditioned design-defect liability on the adequacy of Mutual's FDA-mandated warnings—which *Mensing* makes clear Mutual likewise was powerless to alter. 131 S. Ct. at 2574-75.

Indeed, New Hampshire law is crystal clear about this. *First*, it incorporates warnings into its general risk-utility calculus for *all* design-defect cases. *Chellman*, 637 A.2d at 150 ("If the design of a product makes a warning necessary to avoid an unreasonable risk of harm from a foreseeable use, the lack of warning or an ineffective warning causes the product to be defective and unreasonably dangerous."). That is why the jury instructions

(which respondent concedes were "proper," Red Br. 24) provided that liability could be imposed *only* if "a warning was *not* present and effective to avoid [an] unreasonable danger." JA539. The verdict thus condemned both the drug's FDA-mandated active ingredient (violating *Mensing*'s rationale) and its FDA-mandated warnings (violating *Mensing*'s holding).

Second, with regard to pharmaceuticals in particular, New Hampshire's design-defect law follows comment k, which in respondent's own words renders prescription drugs "exempt from strict liability" if "'properly prepared, and accompanied by proper directions and warning.'" BIO 4 (quoting *Restatement (Second) of Torts* § 402A (1965), cmt. k); Blue Br. 34-36.

Respondent now claims Mutual waived the warnings-related aspects of its preemption argument. But this Court can reverse purely on the ground that Hatch-Waxman's sameness mandate barred Mutual from altering the sulindac molecule, and respondent's waiver claim is baseless in any event. Throughout the proceedings, Mutual argued that the sameness mandate preempts any claim challenging generic warnings, starting with its motion for judgment on the pleadings. Blue Br. 21 (discussing Mutual's argument and the court's erroneous response that Mutual could alter its labeling unilaterally). And at summary judgment, Mutual expressly tied this argument to respondent's design-defect claim: "[D]rugs are unavoidably unsafe products, and as such, cannot be defective in design as long as they are accompanied by adequate warnings. As such, any design claim directly

implicates warnings and thus, falls under the same preemption analysis." Preemption MSJ, 2010 WL 1371985, at 31 (citation omitted).

The trial court expressly *agreed* with Mutual that New Hampshire follows comment k, and that this rendered the adequacy of Mutual's FDA-mandated warnings dispositive. PA128a. But it denied summary judgment *solely* because "the adequacy of Sulindac's safety warning is a matter of genuine dispute" requiring trial. *Id.* That was error: Its holding that the adequacy of Mutual's warnings presented a triable issue of fact necessarily depended on rejecting Mutual's purely legal argument that Hatch-Waxman's sameness requirement places the adequacy of generic warnings beyond state law's reach—a conclusion the court reached without the benefit of this Court's subsequent decision in *Mensing*. PA140a (affirming prior rejection of Mutual's warnings-based arguments, PA142-202a). Indeed, the district court cited as authority the very appellate court decisions *Mensing* reversed. *Id.* Had the trial court not made the very error *Mensing* corrected, but instead recognized that Hatch-Waxman's sameness mandate forecloses any challenge to the adequacy of generic product warnings, its holding that comment k rendered the adequacy of Mutual's warnings dispositive would have entitled Mutual to summary judgment.

Mutual's subsequent withdrawal of its comment k *defense* "'for purposes of the trial,'" Blue Br. 23 (quoting record), has no bearing on the purely legal comment k *argument* Mutual advanced at summary judgment. Mutual's point is and always was that Hatch-Waxman's sameness mandate established the

adequacy of its warnings *as a matter of law*, and thus that there was no basis for holding a trial at all. Mutual never retreated from this argument, and given this Court's eventual decision in *Mensing*, Mutual was entitled to reversal *from the moment the court denied summary judgment*.

As for respondent's claim that Mutual needed to renew this argument at Rule 50, Red Br. 31, it is well-settled that purely legal claims rejected at summary judgment need not be renewed. *Chemetall GMBH v. ZR Energy, Inc.*, 320 F.3d 714, 719-20 (7th Cir. 2003) (collecting cases); *Ruyle v. Continental Oil Co.*, 44 F.3d 837, 841 (10th Cir. 1994) (same). Respondent's cases do not remotely suggest otherwise. *Rekhi v. Wildwood Indus., Inc.*, 61 F.3d 1313 (7th Cir. 1995), actually *rejected* waiver claims because renewing the summary-judgment argument was unnecessary "to avoid unfair surprise [or] give the district court an opportunity to correct its own errors." *Id.* at 1318. Those factors are irrelevant here.[3] And unlike *Exxon Shipping Co. v. Baker*,

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[3] Indeed, Mutual gave both respondent and the court "multiple notices of, and a full opportunity to meet, the argument." *TVT Records v. Island Def Jam Music Group*, 412 F.3d 82, 88 n.4 (2d Cir. 2005). Mutual repeatedly pressed its warnings-based arguments in dispositive motions, *supra*; at the charge conference, 9/2/2010 Tr. at 53 (The Court: "How is preemption even an issue anymore?" Mutual: "We shouldn't be here at all."); and indeed post-trial (albeit in reply), where the court again made clear it "would reject Mutual's argument on the merits, for the reasons explained in its earlier opinion" and the Fifth Circuit's soon-to-be-reversed decision in *Demahy*. PA74-75a. No one can claim "unfair surprise," and Mutual gave the court ample opportunity to correct its error—to no avail.

Mutual's preemption argument was not based on "newly cited statutes" raised "for the first time 13 months after ... verdict," 554 U.S. 471, 486-87 (2008), but on the federal sameness requirement invoked from the outset. Mutual fully preserved this argument. *City of St. Louis v. Praprotnik*, 485 U.S. 112, 120 (1988).

Respondent's claim that Mutual waived its alleged "challenge to the jury instruction" fares no better, Red Br. 30-31, because Mutual is not "challeng[ing] the jury instruction" under New Hampshire law—which it faithfully reflected. *Price*, 702 A.2d at 333; *Vautour*, 784 A.2d at 1182. The problem instead is with New Hampshire law itself, which (as the instruction accurately stated) required exactly what Mutual always said *Mensing* prohibits: a finding that sulindac's FDA-mandated warnings were inadequate. Respondent's assertion that Mutual was required "to seek an appropriate instruction" thus is baffling, Red Br. 31; Mutual's point is and always was that there never should have been a jury to instruct.

Waiver aside, respondent ultimately claims the instruction is irrelevant because "the basis for liability remains the product's overall dangerousness, not the warning." *Id.* 32; *id.* 35-36. But the First Circuit rejected that assertion, explaining that the warning's alleged inadequacy in fact was critical:

> [T]he label was relevant to the design defect claim since, although unalterable by Mutual, its arguable inadequacies put limits on the extent to which [sulindac's] dangerousness was offset by adequate warnings; *so the lack of*

> *a clearer warning made the product itself more dangerous under the risk-benefit test prescribed by* Vautour. The district court's instructions, in a section covering 'The Warning' [JA539] did make clear that this was the relevance of the label.

PA18a. This holding explains why even respondent ultimately concedes the jury had to consider the "warning's potential to lower a product's risks" in its design-defect calculus. Red Br. 32 (citing *Vautour*, 784 A.2d at 1182).[4]

There is thus no dispute that New Hampshire law made the adequacy of Mutual's FDA-mandated warnings an essential component of the design-defect standard.[5] Indeed, that is why respondent repeatedly attacked Mutual's FDA-mandated label in her case-in-chief. Blue Br. 23-25. Whether viewed

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[4] Respondent seeks to mute this concession by concocting a distinction between the warning's "effect" and its "adequacy." Red Br. 36. But that is not what the appellate court said, and respondent's own cases foreclose that distinction. *Cheshire Med. Ctr. v. W.R. Grace & Co.*, 49 F.3d 26, 32 (1st Cir. 1995) ("The existence *and adequacy of a warning* is relevant not only to a warning defect claim, but also to a design defect claim.") (cited at Red Br. 33 n.18).

[5] It thus is irrelevant that this Court distinguished between the preemptive consequences of design-defect and failure-to-warn claims in *Bates*. Red Br. 33 (citing *Bates*, 544 U.S. at 444, 453). When an express preemption clause covers requirements "*for labeling or packaging*," 544 U.S. at 444 (emphasis original), a verdict's implications for labeling may not matter if (in contrast to this case) a particular claim does not address labeling directly. *Id.* at 445-46.

through comment k or the instructions at a trial that never should have happened, this case was infected with the very conflict *Mensing* found dispositive.[6]

C. The Stop-Selling Theory Is No Solution.

Mutual therefore had two options for avoiding enforcement of New Hampshire's design-defect standard: It could have either (1) altered the drug or its warnings to satisfy state law, and thereby violated federal law; or (2) withdrawn from New Hampshire given the dilemma posed by these directly conflicting standards.

That is a paradigmatic impossibility conflict, and the First Circuit was wrong that withdrawing from the regulated activity somehow resolves it. Blue Br. 37-45. The preemption inquiry pre-supposes that parties engage in the regulated conduct, which is why many preemption cases arise from *pre-enforcement litigation* to enjoin state laws. *See, e.g.*, *Brown*, 554 U.S. at 62; *United States v. Locke*, 529 U.S. 89, 97 (2000); *Gade*, 505 U.S. at 93-94; *Douglas*, 431 U.S. at 270-71. And if preemption is defeated because a party can refrain from the regulated conduct, these cases would have been either dismissed or resolved the other way. State law would trump even when federal law expressly bars

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[6] Respondent now claims "a warning likely would not have made any difference," but that was not her argument below—where she told the jury to find Mutual's FDA-mandated label "'inadequate'" because a reference to SJS/TEN was moved into "'the warning section of the label'" from the previously cross-referenced "'adverse reactions section.'" Blue Br. 23-24 (quoting record).

the regulated party from satisfying state standards; the Supremacy Clause would become irrelevant. *In re Darvocet*, 2012 WL 718618, *3 (E.D. Ky. 2012) ("[T]he idea that [the generic defendants] should have simply stopped selling propoxyphene is an oversimplified solution that could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct."). *Mensing*, however, pointedly refused to embrace "an approach to pre-emption that renders conflict pre-emption all but meaningless." 131 S. Ct. at 2579.

Rather than defend the stop-selling rationale on its own terms, respondent claims Mutual was and remains free to market sulindac in violation of state law; it simply must pay damages. Red Br. 1 ("[T]he only state-law obligation is to compensate consumers for injuries."); *also id.* 20, 45, 50. But that is true in every personal-injury case; virtually without exception, damages are the only available relief. Yet this Court has never hesitated to find damages claims preempted, because "'state regulation can be as effectively exerted through ... damages as through some form of preventive relief.'" *Cipollone*, 505 U.S. at 521 (quoting *Garmon*, 359 U.S. at 247); *Riegel*, 552 U.S. at 324 ("[A] liability award can be ... a potent method of governing conduct.") (quotations omitted).[7] What matters is *the standard* being enforced, not *the relief* sought for a violation. Were it otherwise,

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[7] Even where tort claims might seek injunctive relief—as in nuisance—this Court has rejected distinctions based on the form of relief sought. *Ouellette*, 479 U.S. at 498 n.19.

Mensing would have rejected preemption; after all, those claims merely would have resulted in damages.

Finally, respondent asserts there "*would be*" no conflict with federal law "*if* suspending sales is the state-law duty," Red Br. 38 (emphasis shifted), and she claims this distinguishes *Mensing*, where "state law impose[d] an affirmative duty ... to improve the product's label." *Id.* 39. But she of course denies that suspending sales *actually is* the state-law duty, and her argument in any event hinges on wordplay. Saying PLIVA would have been liable in *Mensing* "for not improving the label" is the same as saying PLIVA would have been liable "for selling a drug with an unimproved label." And saying Mutual is liable "for selling an unreasonably dangerous product" is the same as saying Mutual is liable "for not making the product less dangerous." However you phrase it, liability hinges on a state-law standard that federal law precludes generic manufacturers from satisfying.

That is the paradigmatic impossibility conflict. Indeed, this Court's classic illustration of impossibility is directly on point: It posits a "situation [where] federal orders forbade the picking and marketing of any avocado testing more than 7% oil, [while] the California test excluded from the State any avocado measuring less than 8% oil content." *Florida Lime*, 373 U.S. at 143. That is this case: Hatch-Waxman forbade Mutual from selling generic sulindac *that differed materially* from brand-name Clinoril®, while New Hampshire's design-defect tort effectively barred the sale of generic sulindac *unless it differed materially* from Clinoril®. If "stop selling" is an answer, *Florida Lime*'s oft-cited

explanation of impossibility is wrong. Yet that formulation has stood the test of time, and it makes clear the stop-selling evasion is no answer where state and federal standards irreconcilably conflict.

D. The Government's Misbranding Theory Is Unavailing.

The United States unqualifiedly agrees that federal law preempts respondent's claim. U.S. Br. 14. It nonetheless proceeds to address the hypothetical question whether "a 'pure' design-defect claim under another State's law that did not consider labeling would be preempted." *Id.* It answers that "such a claim would be preempted unless the claim was based on new and scientifically significant information that rendered the drug misbranded under [the FDCA]." *Id.* 21.

As the government concedes, "this Court ... need not decide" that question here. *Id.* 20. To the best of Mutual's knowledge, no state recognizes such a claim. And barring a revolution in the law—roughly 40 states recognize a version of comment k, Blue Br. Add. B—it is doubtful any state will. Lest silence be mistaken for agreement, however, two points bear mention here. First, the government unsuccessfully advanced virtually the same theory in *Mensing*—where it claimed the plaintiffs' failure-to-warn claims survived preemption because they mirrored the misbranding statute. U.S. Br., *Mensing*, 25-30. The government's brief, however, does not reconcile its theory with *Mensing*'s failure to embrace the analogue.

Second, the government's theory is based on a seeming contradiction. Because the statute invoked by the government deems a drug misbranded if it is

"dangerous to health when used in the dosage or manner, or with the frequency or duration *prescribed, recommended, or suggested in the labeling thereof*," 21 U.S.C. § 352(j), it is hard to see how a hypothetical "'pure' design-defect claim ... *that d[oes] not consider labeling*," U.S. Br. 20, could parallel that statute. Again, however, the government's brief fails to address this issue. As a result, we respectfully submit that resolution of the hypothetical question raised by the government should await a future case that squarely presents it.[8]

II. Respondent's Claim Frustrates The FDCA's Purposes And Objectives.

Impossibility aside, respondent's claim thoroughly undermines the FDCA's core purposes and objectives. It sanctions precisely what Congress encouraged. And it otherwise thwarts Congress's decision to centralize drug withdrawal decisions in

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[8] To the extent respondent attempts to shoehorn her way into this theory, Red Br. 57-58, the government's misbranding theory is completely different from a New Hampshire design-defect claim. U.S. Br. 20-21. And in any event, respondent did not produce "new and scientifically significant information that rendered [sulindac] misbranded." *Id.* 21. She now invokes a so-called "critical new document revealing sulindac's high adjusted reporting rate for SJS/TEN" relative to other NSAIDs. Red Br. 42. But the government had the data on which the draft was based. U.S. Br. 27, 30 (citing JA 297-98, JA366). And the district court itself deemed the draft "unreliable," 8/20/10 Trial Tr. 31, 38, 41—as did one of its authors, who explained the statements respondent touts were removed before publication because they likewise were considered "unreliable." D. Ct. Dkt. No. 236-7, ¶5.

FDA—which repeatedly has concluded that sulindac should remain available despite its known risks.[9]

A. The Stop-Selling Theory Undermines Hatch-Waxman.

Respondent claims that Mutual's "obstacle preemption arguments lack any statutory basis." Red Br. 43 (capitalization omitted). But Mutual's brief addressed a litany of specific statutory provisions manifesting Congress's intent to both encourage and ensure the sale of affordable generic drugs—with *the same design* and *the same labeling*—whenever their brand-name equivalents come off patent. Blue Br. 46-53.

Respondent's only answer is that Hatch-Waxman does not promote the sale of less-expensive drugs "at all costs." Red Br. 16, 55 n.33, 55-56. But no one is arguing Hatch-Waxman takes a no-holds-barred approach to lowering healthcare costs. As the government explains (U.S. Br. 24-28), Hatch-Waxman's specific statutory provisions require generic design and warnings to be "the same as" their approved branded equivalents—and thus to present *the same risk-benefit profile* embraced by FDA's experts. It is this "special, and different, regulation of generic drugs that allowed the generic

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[9] Respondent's waiver claim is frivolous. Mutual's petition clearly raised purposes-and-objectives arguments. Pet. 31-32. And obstacle preemption is also "fairly included" in the question presented, S. Ct. R. 14(1)(a), which in relevant part asked "Whether the First Circuit erred when it ... held ... that federal law does not preempt state law design-defect claims targeting generic pharmaceutical[s]." Pet. i.

drug market to expand," *Mensing*, 131 S. Ct. at 2582, and the statute's rigorous sameness requirement that led to "acceptance of, and trust in, generic drugs." *Id.* at 2593 (Sotomayor, J., dissenting).

Design-defect claims undermine Congress's carefully calibrated regime by effectively demanding a manufacturer "abandon a market it has been approved by FDA to enter in order to avoid violating ... state tort law." U.S. Br. 28. Indeed, such claims pose the very risks identified by the *Mensing* dissent, without any of the benefits. While different liability rules for generic and branded drugs arguably "threaten to reduce consumer demand for generics," 131 S. Ct. at 2593, state claims that effectively demand withdrawal of generics threaten to leave consumers *without any generic to demand*, "depriving individuals of access to a drug that FDA has determined is safe and effective for sale in the national market." U.S. Br. 29. That is "directly at odds with the Hatch-Waxman Amendments' goal of increasing consumption of generic drugs." *Mensing*, 131 S. Ct. at 2593 (Sotomayor, J., dissenting).[10]

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[10] Respondent says these concerns are overblown because "drug manufacturers have been subject to design-defect liability for decades." Red Br. 50. But of the four cases she marshals, *id.* 4 n.3, three were comment k cases which turned on warnings. *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 655-60 (1st Cir. 1981); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 140 & n.26 (3d Cir. 1973); *Leibowitz v. Ortho Pharm. Corp.*, 307 A.2d 449, 457 (Pa. Super. Ct. 1973). And all four cases involved pre-Hatch-Waxman products, not commoditized generics whose slim sales margins can be overwhelmed by a single verdict. This case well illustrates the difference: According to data recently obtained from IMS Health, Mutual's U.S. sulindac

And while the claim in *Mensing* that generic manufacturers should propose labeling changes to FDA arguably furthers the Agency's mission by aiding its decisionmaking, *id.* at 2588, the claim here depends purely on "second-guessing the FDA." PA10a. Respondent says otherwise, Red Br. 41-42, 52, but again, the government had the data, and the district court repeatedly declared the draft she touts to be "unreliable." *Supra* n.8. Her continued appeal to junk science only underscores the danger in sending these claims before an understandably sympathetic jury. *Riegel*, 552 U.S. at 325; U.S. Br. 28 ("[Second-guessing FDA] would undermine [its] drug-safety determinations, which are made based on sound scientific judgments by an expert federal agency with appropriate access to pertinent safety data.").

As for respondent's claim that damages actions "complement" the statute, Red Br. 40, because they do not actually force "withdrawal of sulindac from interstate commerce," *id.* 50 (quotation omitted), that is true of any claim. A verdict in *Geier*, for instance, would not have compelled Honda to stop selling the Accord; the plaintiff's negligence and design-defect claims merely sought damages because the car lacked airbags. 529 U.S. at 881. The Court found obstacle preemption anyway: Federal law "allow[ed] manufacturers to choose among different passive restraint mechanisms," *id.* at 878, and the

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sales totaled less than $7 million in 2005 (when respondent developed SJS/TEN). Left uncorrected, this single verdict would erase *over three years* of Mutual's *nationwide* sulindac revenues.

plaintiff's tort claims "in effect" created an airbag-only "duty" that "presented an obstacle to the variety and mix of devices that the federal regulation sought." *Id.* at 881.

The case for obstacle preemption is far stronger here. Federal law gave Honda *the option* of installing airbags, so it could have complied with the state standard. But Mutual had *no option* to comply: "[A] brand-name drug and its generic copy must always be the same." *Mensing*, 131 S. Ct. at 2575 (quotation omitted). Respondent says *Geier* is irrelevant because it involved "a 'specific agency regulation bearing the force of law.'" Red Br. 48 (quoting *Wyeth v. Levine*, 555 U.S. 555, 580 (2009)). But Hatch-Waxman's sameness mandate *is the law*, and one need not "wade[] into a sea of agency musings," *Williamson v. Mazda Motor of Am., Inc.*, 131 S. Ct. 1131, 1142 (2011) (Thomas, J., concurring), to recognize that it seeks to "increas[e] consumption of generic drugs" which are the same as their FDA-approved branded equivalents. *Mensing*, 131 S. Ct. at 2593 (Sotomayor, J., dissenting).

B. The Stop-Selling Theory Undermines The Broader FDCA.

Respondent's claim also undermines the broader FDCA, which centralizes authority to compel the withdrawal of approved drugs in FDA and balances that authority with strong due-process protections. Blue Br. 53-58; U.S. Br. 24-30. There is thus no merit to respondent's assertions that FDA is merely a "gatekeeper," Red Br. 1, that does not "confer ... an affirmative right to market drugs." *Id.* 43. FDA long ago recognized that ANDA approval confers "rights and privileges that [are] constitutionally

protected," 54 Fed. Reg. 28872, 28904 (1989), and the statutory evolution of FDA's withdrawal authority makes clear that Congress put the Agency in charge of both opening the proverbial "gate" *and closing it*.

Wyeth is not to the contrary. That case had no occasion to consider the stop-selling theory or the evolution of FDA's withdrawal authority over decades. Blue Br. 53-62. As *Mensing* recognized, *Wyeth* instead turned on the fact that federal law specifically allowed Wyeth to alter its label unilaterally. *Wyeth*, 555 U.S. at 571. It thus could not be said that initial FDA approval "established a specific labeling standard that leaves no room for different ... judgments," *id.* at 575, because federal law expressly empowered brand companies to deviate from FDA's *initial* labeling and thereby ensured they could accommodate different judgments about labeling. *Id.* at 583 (Thomas, J., concurring) ("[Federal laws] do not give drug manufacturers an unconditional right to market their federally approved drug at all times *with the precise label initially approved by the FDA*."). By contrast, Mutual *never* had authority to deviate from Hatch-Waxman's sameness requirement—and it would fundamentally undermine the statute's careful delegation of withdrawal authority to FDA if state law effectively could demand withdrawal of FDA-approved drugs precisely because they comply with federal standards from which no deviation is lawful.

CONCLUSION

The judgment should be reversed.

March 12, 2013

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AMICUS CURIAE BRIEF

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MUTUAL PHARMACEUTICAL COMPANY, INC.,
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v.

KAREN L. BARTLETT

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, preempts a state-law product liability claim that asserts that a drug approved as safe and effective by the Food and Drug Administration is defectively designed because its active ingredient is claimed to be unreasonably dangerous for its approved uses.

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INTEREST OF THE UNITED STATES

This case concerns whether federal law preempts a state-law tort claim alleging that a generic prescription drug approved by the Food and Drug Administration (FDA) pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, is unreasonably dangerous. By virtue of FDA's regulatory responsibilities, the United States has a substantial interest in the resolution of the preemption issue.

STATEMENT

1. A manufacturer must apply for and secure FDA approval to market a "new drug" in interstate commerce. 21 U.S.C. 355(a); see 21 U.S.C. 321(p) (defining "new drug"). FDA approves two categories of such applications: a new drug application (NDA) for brand-

name drugs, and an abbreviated new drug application (ANDA) for generic versions of brand-name drugs. See 21 U.S.C. 355(a), (b) and (j).

a. Before a manufacturer may submit an NDA, it generally must submit an investigational new-drug application for, and conduct, clinical trials to investigate the drug's safety and efficacy. 21 U.S.C. 355(i); 21 C.F.R. 312.20-312.21; see *Merck KGaA* v. *Integra Lifescis. I, Ltd.*, 545 U.S. 193, 196 (2005). The investigational new-drug application must include, *inter alia*, pre-clinical research regarding the drug's safety based on "pharmacological and toxicological studies of the drug involving laboratory animals or in vitro." 21 C.F.R. 312.23(a)(8). The clinical trial process is designed to elicit reliable and comprehensive scientific evidence regarding the drug's safety and efficacy.

If the clinical trials demonstrate safety and efficacy, the manufacturer may submit an NDA. The NDA must contain, *inter alia*, extensive information about the composition, manufacture, and specifications of the drug, "full reports of [the clinical] investigations," 21 U.S.C. 355(b)(1)(A), relevant non-clinical studies, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source," 21 C.F.R. 314.50(d)(1)-(2) and (5)(iv). The application must also contain "the labeling proposed to be used for such drug," 21 U.S.C. 355(b)(1)(F); see 21 C.F.R. 314.50(c)(2)(i), and "a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling," 21 C.F.R. 314.50(d)(5)(viii); see 21 C.F.R. 314.50(c)(2)(ix).

FDA may approve the NDA only if it determines, *inter alia*, that (i) the drug is, in fact, "safe for use" under

"the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," and (ii) "substantial evidence" shows that "the drug will have the effect it purports or is represented to have" under the conditions of use in the proposed labeling. 21 U.S.C. 355(d). Because "[n]o drug is absolutely safe" and "all drugs have side effects," FDA, *FDA's Drug Review Process: Continued* (Mar. 13, 2012), http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm289601.htm, FDA "generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use," *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979), *i.e.*, the drug's "probable therapeutic benefits must outweigh its risk of harm," *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000).

b. After a brand-name drug's NDA has been approved and officially listed by FDA (see 21 U.S.C. 355(j)(7)), and subject to certain periods of exclusivity (see 21 U.S.C. 355(j)(5)(F)), any manufacturer may seek approval to market a generic version of the drug under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, known as the Hatch-Waxman Amendments. Those Amendments prescribe a process for submitting an ANDA for a generic drug, 21 U.S.C. 355(j), and were designed to balance encouraging drug development with accelerating the availability of lower-cost generic alternatives to brand-name drugs. See H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. 1, at 14-15 (1984) (*House Report*).

The ANDA approval process does not require the manufacturer to provide independent evidence of a generic drug's safety or efficacy. Instead, an ANDA must generally show that the generic drug is the relevant

brand-name drug's "pharmaceutical equivalent" (*i.e.*, it has the "same" active ingredient(s), route of administration, dosage form, and strength) and "bioequivalent" (*i.e.*, it has the equivalent "rate" and "extent" of absorption), and that it is labeled for the same conditions of use previously approved for the brand-name drug. 21 U.S.C. 355(j)(2)(A)(ii)-(iv) and (8)(B); 21 C.F.R. 320.1(c); see FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* vi-vii (32d ed. 2012) (*Orange Book*) ("pharmaceutical equivalents"). The generic drug must also have the "same" labeling as its brand-name counterpart, with exceptions not relevant here. 21 U.S.C. 355(j)(2)(A)(v). Those sameness requirements reflect the fundamental premise of the ANDA process: A generic drug can be relied upon to be as safe and effective as its brand-name counterpart for its approved conditions of use. See 54 Fed. Reg. 28,884 (1989); *Orange Book* vii ("therapeutic equivalents").

c. After FDA has approved an NDA or ANDA, the manufacturer may not unilaterally make any major changes to the conditions established by FDA's approval for a drug—whether brand-name or generic—such as major "changes in the qualitative or quantitative formulation of the drug product, including active ingredients." 21 C.F.R. 314.70(b)(2)(i); see 21 C.F.R. 314.3 ("drug substance"). Changes that would create a different active ingredient require approval of an NDA prior to interstate marketing. See FDA, *Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees* 3 (Dec. 2004), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf ("Every different active ingredient

* * * should be submitted in a separate original application.") (footnote omitted).

After an NDA or ANDA is approved, the applicant must maintain records and make reports to the Secretary. 21 U.S.C. 355(k)(1). An applicant must, *inter alia*, promptly report to FDA serious adverse events associated with use of its drug in humans and periodically submit certain new information that may affect FDA's previous conclusions about the drug's safety or effectiveness. 21 C.F.R. 314.80, 314.81, 314.98. The FDCA provides that the Secretary shall withdraw approval of a drug—brand-name or generic—if, *inter alia*, she determines that scientific data show that the drug is "unsafe for use" under the conditions stated in its labeling or may not have its purported effect. 21 U.S.C. 355(e).[1] FDA has informed this Office, however, that more typically when FDA advises the manufacturer that significant new adverse information changes the risk/benefit profile of the drug in a manner that cannot adequately be addressed through labeling changes or through FDA's other authorities, the manufacturer withdraws the product from the market. Also, since 2007, the Secretary has had authority in certain circumstances to require a brand-name drug manufacturer to conduct post-approval studies or clinical trials to assess indications of serious safety risks, or to order any drug manufacturer to make labeling changes to address new safety information. 21 U.S.C. 355(*o*)(2)(B), (3) and (4) (Supp. V 2011).

The FDCA prohibits the manufacture or distribution of any drug that is misbranded. 21 U.S.C. 331(a)-(c), (g)

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[1] The Secretary may suspend approval of a drug without notice or hearing if she finds an "imminent hazard" to public health. 21 U.S.C. 355(e).

and (k). A drug is misbranded if, *inter alia*, it is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. 352(j). That provision applies to any "drug," whether or not it has been approved by FDA. 21 U.S.C. 321(g)(1), 352.

2. In 1978, FDA approved an NDA for a nonsteroidal anti-inflammatory drug (NSAID) with the nonproprietary name sulindac and the brand name Clinoril. Ten years later, FDA approved the first of several ANDAs for generic sulindac and, in 1991, approved petitioner's ANDA for sulindac. Pet. App. 3a, 144a-145a.

NSAIDs, including sulindac, are known in rare instances to cause a hypersensitivity reaction called Stevens-Johnson Syndrome (SJS) and a more severe manifestation of that syndrome called toxic epidermal necrolysis (TEN). Pet. App. 3a, 23a. FDA-approved labeling for Clinoril at the time of respondent's injury in 2004 expressly listed both "Stevens-Johnson syndrome" and "toxic epidermal necrolysis" as possible "Adverse Reactions." J.A. 554. The drug's FDA-approved "Warnings" section did not refer to SJS/TEN by name, but it referred back to the Adverse Reactions section in warning that rare "hypersensitivity (see ADVERSE REACTIONS)," including "severe skin reactions[,] have occurred during therapy with sulindac," and that "[f]atalities have occurred in these patients." J.A. 553; Pet. App. 109a. The labeling for generic sulindac, including petitioner's sulindac, must be the same as that of Clinoril with exceptions not relevant here. See p. 4, *supra*; *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2577 (2011).

Subsequently, in 2005, FDA completed a "comprehensive review of the risks and benefits, including the risk of SJS and TEN, of all NSAID products." Decision Letter, FDA Docket No. 2005P-0072/CP1, at 2 (June 22, 2006), http://www.fda.gov/ohrms/dockets/dockets/05p0072/05p-0072-pav0001-vol1.pdf. That review led FDA to recommend changes to the labeling of all NSAIDs, including sulindac. J.A. 353-354, 364, 557, 580 & n.8; see FDA, *COX-2 Selective and Non-Selective NSAIDS* (Nov. 27, 2012), http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm103420.htm. FDA's updated "Labeling Template" for prescription NSAIDs modified the Warnings section to state, *inter alia*:

> NSAIDs, including [the labeled drug], can cause serious skin events such as * * * Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. * * * Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

See *ibid.* (providing link to *Labeling Template* 3). The labeling for Clinoril and the generic forms of sulindac, including petitioner's sulindac—like the labeling for all other prescription NSAIDs—was updated accordingly. See J.A. 353, 364, 555; C.A. App. 2244.

3. a. In December 2004, respondent's doctor prescribed respondent Clinoril for shoulder pain. Respondent's pharmacist dispensed petitioner's generic sulindac. Respondent soon developed an extreme case of TEN in which 60-65 percent of the surface of her body deteriorated, was burned off, or turned into an open wound. Respondent spent months in a medically induced coma,

endured 12 eye surgeries, and was tube-fed for a year. Respondent is now severely disfigured, has a number of physical disabilities, and is nearly blind. Pet. App. 3a, 22a-23a.

b. Respondent sued petitioner in New Hampshire state court, and petitioner removed the case to federal district court. Pet. App. 3a. Respondent asserted numerous state-law claims, including failure-to-warn and design-defect product-liability claims. *Ibid.* The district court dismissed respondent's failure-to-warn claim because her "prescribing doctor admitted that he had not read the box label or insert." *Id.* at 4a. By trial, only respondent's design-defect claim remained. *Id.* at 3a. As relevant here, the district court rejected petitioner's contention that the design-defect claim was preempted by the FDCA, concluding that petitioner could comply with both state and federal law, if they differed, by refraining from distributing sulindac at all (in New Hampshire). Pet. App. 164a-166a.

A "product design" is "unreasonably dangerous" and hence defective under New Hampshire tort law, regardless whether a safer design is possible, if "the magnitude of the danger outweighs the utility of the product" in light of the "usefulness and desirability of the product to the public as a whole" and "the presence and efficacy of a warning to avoid an unreasonable risk of harm." *Vautour* v. *Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001) (citation omitted). Under comment *k* to Section 402A of the Restatement (Second) of Torts (comment *k*), which New Hampshire courts have adopted, design-defect liability may not be imposed with respect to a product that is "unavoidably unsafe" if the product is "highly useful" and has "an adequate safety warning." Pet. App. 7a (citation omitted).

At trial, respondent presented expert evidence based on spontaneous adverse-event reports to FDA and other information that, respondent asserted, suggested that sulindac was more likely to cause SJS/TEN than other available NSAIDs and that sulindac's overall safety profile was similar to several drugs withdrawn from the market. Pet. App. 4a-5a. Respondent also introduced the labeling for petitioner's sulindac, including the labeling as revised to include an express reference to SJS/TEN in the Warning section itself. J.A. 555-556. Petitioner cross-examined respondent's witnesses but withdrew reliance on a comment *k* defense and did not present its own affirmative case. Pet. App. 5a, 7a.

The district court instructed the jury that, to prevail on her defective-design claim, respondent must prove that "[s]ulindac's design" was "unreasonably dangerous," *i.e.*, that "the danger [from its use] outweighs the utility or usefulness of the product" "to the public as a whole." J.A. 512-513. The court further explained that respondent "must prove that the product was unreasonably dangerous even with its warning" and that the jury could find "a defect in design" only if it found that "[s]ulindac was unreasonably dangerous and that a warning was not present and effective to avoid that unreasonable danger." J.A. 514. The jury was also instructed that no design defect exists if "a warning was present and effective to avoid that unreasonable danger." *Ibid.*

The district court described to the jury numerous "FDA requirements for [drug] labels," including the order in which adverse reactions should be listed in labeling, J.A. 516-518, and instructed the jury that it could consider "FDA's requirements for drug labels" when determining whether sulindac's labeling gave an

effective "warning to avoid an unreasonable risk of danger from foreseeable uses of the product." J.A. 516. The court further instructed the jury that it could consider the evidence that FDA had "approved [s]ulindac as safe and effective for its intended uses" and had "approved [s]ulindac's label," but that the jury was free to give FDA's approval "as much or as little weight as you think it deserves, in light of all of the evidence." J.A. 515.

In light of those instructions, respondent's counsel argued to the jury that petitioner's labeling for sulindac did not provide an "effective" warning to make sulindac reasonably safe, because "serious adverse reactions" "must be in the warning section of [a drug] label"; petitioner's labeling was "in violation of the law" at the time respondent was injured because it did not sufficiently indicate that sulindac could cause SJS and TEN; and the fact that "[petitioner] was forced to change its ineffective warning to add SJS and TEN * * * after [respondent] was prescribed the drug" demonstrated that petitioner's "label [wa]s ineffective" before that change. C.A. App. 1867-1868, 1870, 1898; see *id.* at 1883, 1899-1902.

Counsel further argued that sulindac was a "needless and useless drug" with the highest adjusted "reporting" rate of SJS/TEN amongst all NSAIDs. *E.g.*, C.A. App. 1863, 1871-1872, 1877, 1883-1885. Counsel asserted that FDA merely "rubber stamped" the ANDA for petitioner's sulindac, and that "no evidence [showed] that FDA has ever done a focused analysis on [s]ulindac" to justify its "be[ing] on the market." *Id.* at 1891. FDA, counsel asserted, lacks "expertise in risk/benefit assessment" and "impos[es] a significant risk to * * * the safety of the public" because it is unable to perform its "mission

to monitor drug safety for any class of drugs." *Id.* at 1892-1894.

The jury found petitioner liable on respondent's defective-design claim and awarded respondent over $21 million in damages. Pet. App. 104a.

c. The court of appeals affirmed. Pet. App. 1a-24a. As relevant here, the court held that the FDCA and FDA's regulations did not preempt respondent's design-defect claim. *Id.* at 8a-11a. The court concluded that the logic of this Court's decision in *Wyeth* v. *Levine*, 555 U.S. 555 (2009), which held that the FDCA did not preempt the failure-to-warn claims advanced there against a brand-name drug manufacturer, "applies to design defect claims as well." Pet. App. 9a. The court acknowledged that "*Wyeth*'s holding was technically limited to failure-to-warn claims," *ibid.*, and that the judgment under state law in this case was based on the jury's "second-guessing" of FDA's "risk-benefit analysis," but it determined that *Wyeth* effectively "resolved the conflict against general preemption." *Id.* at 10a.

The court of appeals recognized that *Mensing* held that failure-to-warn claims are preempted with respect to generic drugs, because FDA regulations currently make it impossible for generic-drug manufacturers to independently change their labels to comply with any state tort-law duty requiring use of a different label. Pet. App. 9a-10a. The court also acknowledged the "force" of petitioner's contention that *Mensing*'s logic applies here, where generic-drug manufacturers also "cannot alter the composition of the drug" in response to a design-defect claim. *Id.* at 10a. But the court found no preemption, because a manufacturer could simply "choose not to make the drug at all" in order to comply with both federal and state law. *Ibid.*

SUMMARY OF ARGUMENT

A. *Mensing*'s holding that the FDCA preempts state-law failure-to-warn claims against generic-drug manufacturers controls this case. Although respondent's claim is denominated a design-defect claim, the duty under New Hampshire law to design a product that is not "unreasonably dangerous" itself includes a state-law duty to provide warnings sufficient to eliminate any unreasonable danger from the product. Respondent's claim, like the claim in *Mensing*, reflects a duty to alter FDA-approved labeling deemed inadequate. As this Court held in *Mensing*, FDA regulations currently prohibit generic-drug manufacturers from making such independent labeling changes, thus preempting respondent's claim.

The court of appeals concluded that petitioner could comply simultaneously with federal and state law by halting its sale of sulindac in New Hampshire. But that reasoning cannot be squared with *Mensing*, which reflects an implicit judgment that the option of withdrawing from a market is not sufficient to defeat impossibility preemption in this context.

B. The Court need not decide whether the FDCA would preempt a "pure" design-defect claim that does not consider the adequacy of labeling. That issue is difficult and close, with several factors weighing in favor of finding no preemption. The government nevertheless concludes that the FDCA would preempt a pure design-defect claim where, as here, the claim does not require the plaintiff to prove that the manufacturer knew or should have known of new and scientifically significant evidence that rendered the drug "misbranded" under federal law.

Congress has required federal drug-safety determinations to be made by an expert federal agency with access to the pertinent safety data on the basis of sound scientific judgments, and FDA's risk-benefit analysis is rigorous. Congress has also charged FDA with ongoing drug-safety monitoring and requires FDA to withdraw its approval of a drug if it determines that the drug is not safe for the conditions of use in its approved labeling.

A State that permitted a pure design-defect claim, however, would require a jury independently to balance the health risks and benefits for an FDA-approved drug to determine if the drug is "unreasonably dangerous." Congress's purposes of ensuring that expert, science-based judgments are made by FDA, and the assurance that FDA approval provides for market participants, would be undermined by ad-hoc reconsiderations on a State-by-State and lawsuit-by-lawsuit basis.

Tort judgments second-guessing FDA's expert drug-safety determination would undermine the federal regime to the extent that they forbade or significantly restricted the marketing of an FDA-approved drug. In this case, respondent's counsel relied on the absence of evidence that FDA was aware of data concerning sulindac's relative safety risk, but, in reality, the underlying data came from FDA; FDA was aware of and considered the publication addressing reporting rates of SJS/TEN on which petitioner relied; FDA conducted a comprehensive review of the risks and benefits of all NSAIDs; and FDA did not conclude that sulindac should be removed from the market.

ARGUMENT

RESPONDENT'S DESIGN-DEFECT CLAIM IS PREEMPTED

Under the Supremacy Clause, state laws that conflict with federal law are preempted. *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 372 (2000); *Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982) ("Federal regulations have no less preemptive effect than federal statutes."). Conflict preemption occurs "where it is impossible for a private party to comply with both state and federal law" or where state law "'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Crosby*, 530 U.S. at 372-373 (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). "[T]he purpose of Congress is the ultimate touchstone in every preemption case." *Wyeth* v. *Levine*, 555 U.S. 555, 565 (2009) (quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 485 (1996)).

This Court's decisions in *Wyeth* and *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011), provide the framework for evaluating this case. In *Wyeth*, the Court held that a state-law failure-to-warn claim—premised on a brand-name-drug manufacturer's state-law duty to strengthen the warning on its FDA-approved labeling—was consistent with federal law and not preempted, because FDA regulations permitted the manufacturer to "add or strengthen" warnings in its labeling to "increase the safe use of the drug" without "wait[ing] for FDA approval," when there was newly acquired evidence that was not available when FDA approved the labeling. 555 U.S. at 565, 568-569 (citation omitted). Two years later, in *Mensing*, the Court reached the opposite result with respect to failure-to-warn claims against generic-drug manufacturers. Those claims were preempted, *Mensing*

held, because FDA's regulations prohibited generic-drug manufacturers from making changes to their FDA-approved labeling without prior FDA approval. 131 S. Ct. at 2574-2575, 2580-2581.[2] It was therefore impossible for the generic-drug manufacturers in *Mensing* independently to comply with a state tort-law obligation to improve their labeling. *Id.* at 2580-2581.

Respondent's design-defect claim rests on the premise that the active ingredient of a drug that FDA approved as safe and effective for its labeled conditions of use was "unreasonably dangerous" in light of its FDA-approved labeling. But like the generic-drug manufacturer in *Mensing*, petitioner could not make changes that created a different active ingredient or strengthened the warning in its generic labeling without FDA's prior approval. The state tort law on which the jury's verdict rests therefore is preempted.

A. Under *Mensing*, It Was Impossible For Petitioner To Comply With State-Law Duties Underlying Respondent's Design-Defect Claim

1. The imposition of liability under state tort law, whether based on a theory of negligence or strict liability, is ultimately "'premised on the existence of a legal duty'" imposed by the State and the defendant's violation of that "state-law obligation." *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 324 (2008) (quoting *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 522 (1992) (plurality opinion)); see *id.* at 320, 323-325 (addressing claims of strict

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[2] This Office has been informed that FDA is considering a regulatory change that would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances. If such a regulatory change is adopted, it could eliminate preemption of failure-to-warn claims against generic-drug manufacturers.

liability and negligence). Such law, "applied by juries under a negligence or strict-liability standard," is "designed to be[] a potent method of governing conduct and controlling policy." *Id.* at 324-325 (citation omitted).[3]

Respondent's design-defect claim under New Hampshire law is premised on a manufacturer's duty to design a product that is not "unreasonably dangerous." *Vautour* v. *Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1181-1182 (N.H. 2001). That duty, however, does not focus only on physical characteristics of the product itself. In New Hampshire, "[t]he duty to warn is part of the general duty to design * * * products that are reasonably safe." *Chellman* v. *Saab-Scania AB*, 637 A.2d 148, 150 (N.H. 1993). For that reason, a "product design" is "unreasonably dangerous" if "the magnitude of the danger outweighs the utility of the product" in light of the "usefulness and desirability of the product to the public as a whole" *and* "the presence and efficacy of a warning to avoid an unreasonable risk of harm." *Vautour*, 784 A.2d at 1182 (citation omitted). State law that turns on the adequacy of a generic drug's labeling conflicts with federal law under *Mensing*, quite aside from issues concerning the design of the product itself.

Because "[t]he duty to warn *is part of* the general duty to design" non-defective products in New Hampshire, *Chellman*, 637 A.2d at 150 (emphasis added), the jury had to consider "the presence and efficacy of a warning

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[3] Whether a State chooses to define the scope of its tort duties as elements of a plaintiff's cause of action, a defendant's defense, or a combination thereof is immaterial. "When a person has a substantive defense in law to an action," that legal defense simply establishes that "the conduct of which complaint is made is not a breach of duty." Glanville Williams, *The Concept of Legal Liberty*, 56 Colum. L. Rev. 1129, 1129 (1956).

to avoid an unreasonable risk of harm" when deciding whether petitioner's generic sulindac *as labeled* was unreasonably dangerous. See *Vautour*, 784 A.2d at 1182. Thus, the state-law duty to design a non-defective product *includes* a duty to provide an adequate warning. But with respect to generic drugs, any state-law demand to "use a different, stronger label" for a generic drug to avoid liability is preempted by federal regulations currently forbidding generic-drug manufacturers from independently changing their labeling. *Mensing*, 131 S. Ct. at 2577, 2579.

The record shows that the hybrid design-and-warning nature of New Hampshire design-defect law underlies the verdict below. The district court specifically instructed the jury that a "defect in design" exists only if "a warning was not present and effective to avoid [an] unreasonable danger" from use and that, if "a warning was present and effective to avoid that unreasonable danger, then [the jury] must find for [petitioner]." J.A. 514. Respondent's counsel likewise argued at length to the jury that petitioner's labeling was insufficient to warn of the risk of SJS/TEN at the time of respondent's injury and that the subsequent FDA-approved labeling change itself showed that respondent's labeling was ineffective. See p. 10, *supra*; cf. p. 7, *supra* (explaining labeling change for all prescription NSAIDs, not just sulindac).

Nor is this feature of product-liability law unique to New Hampshire. A defective-drug-design claim often overlaps with a failure-to-warn claim, and whether a drug is unreasonably dangerous is typically considered in light of the adequacy of accompanying warnings. See Restatement (Second) of Torts § 402A cmt. k, at 353-354 (1965) (it is "especially common in the field of drugs" for

products to be "incapable of being made safe for their intended and ordinary use" and "for this very reason cannot be legally sold except * * * under the prescription of a physician"; "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous"); *Bruesewitz* v. *Wyeth*, 131 S. Ct. 1068, 1077 n.41 (2011) (noting that, as of 1986, "a large number of courts" took comment *k* to mean that manufacturers "did not face strict liability for side effects of properly manufactured prescription drugs that were accompanied by adequate warnings"); *Kurns* v. *Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1268 (2012) (discussing Restatement (Third) of Torts: Products Liability § 2(c), at 14 (1998) (*Third Restatement*)); Pet. Br. Addendum B (listing States that follow comment *k*).

2. The court of appeals concluded that impossibility preemption of respondent's design-defect claim was defeated because petitioner could comply simultaneously with state and federal law simply by deciding not "to make the drug and market it in New Hampshire." Pet. App. 10a-11a. But that reasoning cannot be reconciled with *Mensing*'s conclusion that it was "impossible" for the manufacturer to comply with a state-law duty to change its labeling because federal law prohibited the change. *Mensing*'s reasoning presupposed that the generic product would be on the market and that the relevant question for preemption purposes was whether state law could require the manufacturer to change the labeling of the drug it was selling.

In fact, the Eighth Circuit in *Mensing* had grounded its no-impossibility-preemption holding in part on the rationale that generic-drug manufacturers "were not compelled to market [the drug at issue]" and thus "could

have simply stopped selling the product" in order to comply with different state-law labeling duties. *Mensing* v. *Wyeth*, 588 F.3d 603, 611 (8th Cir. 2009), rev'd, 131 S. Ct. 2567 (2011). This Court's decision reversing the Eighth Circuit's judgment did not expressly address that reasoning, but the Court presumably was aware of it.[4] Although the Court sometimes grants review "to decide particular legal issues while assuming without deciding the validity of antecedent propositions," *Domino's Pizza, Inc.* v. *McDonald*, 546 U.S. 470, 478-479 (2006) (citation omitted), *Mensing* is reasonably understood as reflecting an implicit judgment that a manufacturer's ability simply to withdraw from marketing the drug was not a sufficient basis to defeat impossibility preemption of the failure-to-warn claim there.[5]

This conclusion is reinforced by the fact that *Wyeth* also appears to have rested on a similar assumption. Were the court of appeals' stop-selling rationale valid, *Wyeth*'s analysis of FDA's changes-being-effected (CBE) regulation, which allows brand-name-drug manufacturers to make certain labeling changes without prior FDA approval, would have been unnecessary to reject the manufacturer's impossibility-preemption argument.

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[4] Cf. *Mensing*, 131 S. Ct. at 2587 n.8 (Sotomayor, J., dissenting) (noting that "the Eighth Circuit suggested that the Manufacturers could not show impossibility because federal law merely permitted them to sell generic drugs" and "did not require them to do so," but that the respondents "ha[d] not advanced this argument" and the dissent found it unnecessary to consider it).

[5] The *Mensing* respondent petitioned this Court for rehearing specifically on the ground that the Court's analysis was flawed because drug manufacturers "could have satisfied their duty under state tort law by suspending sales." Pet. for Reh'g, at 2-3, *Mensing*, *supra* (No. 09-993) (citing *Mensing*, 588 F.3d at 611). The Court denied rehearing. 132 S. Ct. 55 (2011).

See 555 U.S. at 568-573. In particular, the Court stressed that Wyeth had not demonstrated that it was impossible to comply with a state-law duty to change the label because it had not clearly shown that FDA would not have approved such a change, *id.* at 571, 573, thereby implying that impossibility preemption would have been established if Wyeth had made such a showing.

B. Pure Design-Defect Claims Are Preempted Unless Based On New And Scientifically Significant Information That Rendered The Product Misbranded Under Federal Law

Because respondent's design-defect claim under New Hampshire law necessarily turns on the adequacy of the labeling for sulindac, it is preempted under *Mensing*. This Court therefore need not decide whether a "pure" design-defect claim under another State's law that did not consider labeling would be preempted. That is a much more difficult question.

The Restatement (Third) of Torts identifies such a design-defect claim as one assuming the existence of a "reasonable health-care provider[]" who knows all the "foreseeable risks and therapeutic benefits" of the drug. *Third Restatement* § 6(c) & cmts. b and f, at 145, 147, 149. If such a provider, in the exercise of expert medical judgment, would "not prescribe the drug * * * for any class of patients" because its "foreseeable risks of harm" are "sufficiently great in relationship to its foreseeable therapeutic benefits," the drug will provide "net benefits to no class of patients" and is deemed defectively designed. *Id.* § 6(c) & cmt. f, at 145, 149. That test imposes a "very demanding objective standard" that could be met only under "unusual circumstances." *Id.* cmt. f, at 149.

It does not appear that this approach has been accepted in the States to any significant degree, and it has

not been adopted in New Hampshire. See *Vautour*, 784 A.2d at 1182-1184. But if New Hampshire's design-defect tort law were to be reformulated in that manner, it might apply a safety standard triggered when an objective health-care provider knowing all the drug's foreseeable risks and benefits would conclude that "the magnitude of the danger [from using the drug] outweighs the utility of the product" not for "the public as a whole," *id.* at 1182 (citation omitted), but for any class of patients. That test would require a jury to revisit FDA's expert scientific determination, made for the brand-name drug after extensive undertakings by the manufacturers and extensive scrutiny by FDA, that the approved uses of the drug are, in fact, "safe" for the indicated population because the drug's "therapeutic benefits * * * outweigh its risk of harm." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000). Although the question is close, the government concludes that such a claim would be preempted unless the claim was based on new and scientifically significant information that rendered the drug misbranded under 21 U.S.C. 352(j).

Several factors do weigh in favor of finding no preemption even in that context. First, the FDCA makes FDA approval a prerequisite for, *inter alia*, "introduc[ing] or deliver[ing] for introduction into interstate commence" any "new drug." 21 U.S.C. 355(a). That text does not expressly require that an approved drug be made available in any particular State or that the manufacturer be guaranteed the ability to make it so. Second, Congress in 1976 adopted an express preemption provision in the FDCA for medical devices (21 U.S.C. 360k(a)) but has not enacted a similar provision for drugs. Congress's failure to do so, "coupled

with its certain awareness of the prevalence of state tort litigation," reflects a willingness to allow at least certain types of tort actions against drug manufacturers. *Wyeth*, 555 U.S. at 574-575; see *Riegel*, 552 U.S. at 327. Third, design-defect actions are not inherently inconsistent with federal regulation of product safety, and Congress has preserved at least some such actions (and other tort claims) when enacting express preemption provisions in certain other contexts. See, *e.g.*, 21 U.S.C. 379r(e) (FDCA provision governing over-the-counter drugs); *Bates* v. *Dow Agroscis. LLC*, 544 U.S. 431, 439, 447-449 (2005) (pesticide regulation); *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 59, 63 (2002) (boat design); *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 867-870 (2000) (automobile safety); cf. *Bruesewitz*, 131 S. Ct. at 1075-1082 (finding a defective-vaccine-design claim expressly preempted by Vaccine Act without addressing whether the claim would otherwise have been viable). Finally, certain language in *Wyeth* supports the proposition that at least certain state-law tort actions have long been understood to complement FDA drug-safety regulation. See 555 U.S. at 574-579.

Although the foregoing considerations are significant, we nevertheless conclude that in the context of FDA's regulation of new drugs under the FDCA, "pure" state-law design-defect claims would be preempted where state law does not require the plaintiff to prove that the manufacturer knew or should have known of new and scientifically significant evidence that rendered the drug misbranded under federal law. In those circumstances, the ability of a manufacturer to withdraw its product from the market altogether in order to avoid a violation of state law—despite the commitment of resources by the manufacturers of the brand-name and generic prod-

ucts and FDA's extensive evaluations and approvals for the product to enter the national market—should not be deemed sufficient to defeat impossibility preemption. And the application of state law to require that result would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 372-373 (citation omitted).

Our conclusion that the FDCA preempts state-law defective-drug-design claims does not, however, suggest that all state tort claims are preempted. To the contrary, state tort law remains vital in several FDA-approved drug contexts.

First, as *Wyeth* held, state-law failure-to-warn claims may be brought against a brand-name manufacturer that fails to update its labeling in light of newly acquired information as permitted by FDA's CBE regulation. "Failure to instruct or warn is *the* major basis of liability for manufacturers of prescription drugs," *Third Restatement* § 6 cmt. d, at 147 (emphasis added), and that primary basis for liability exists when changes are permitted by FDA's CBE regulation. Cf. p. 16 n.2, *supra* (noting that regulatory change could also allow failure-to-warn actions against generic-drug manufacturers).

Second, appropriate state-law actions that parallel the FDCA's drug "misbranding" prohibition would not be preempted. Under that prohibition, a manufacturer has a federal duty not to market a drug if, *inter alia*, it is "dangerous to health" when used as provided in the labeling. 21 U.S.C. 352(j); see 21 U.S.C. 331(a). A state-law duty not to market the drug in the same circumstances would not conflict with federal law if it appropriately accounted for FDA's role under the FDCA. Cf. *Bates*, 544 U.S. at 447 (state-law pesticide labeling requirement not preempted under express preemption

provision if it is "equivalent to, and fully consistent with, [federal] misbranding provisions"); *Lohr*, 518 U.S. at 495 (express preemption under FDCA in medical-device context). But the jury was not required to find in this case that, notwithstanding FDA's approval of sulindac and its review of its safety in 2005, new evidence concerning the rare occurrence of SJS/TEN rendered sulindac so dangerous as to be misbranded under that federal standard.[6]

Neither of the foregoing theories is available here. And as explained below, a pure design-defect claim, even if New Hampshire law provided for one, would be preempted if not based on new, scientifically significant evidence.

1. Congress has vested FDA with the responsibility to determine when a new drug is "safe" and "effective" under the conditions of use stated in its labeling, so as to warrant the drug entering the interstate market. 21 U.S.C. 355. Because no drug is entirely safe, FDA makes an expert judgment that "a drug [is] safe when the expected therapeutic gain justifies the risk entailed by its use," *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979), *i.e.*, that the drug's likely "therapeutic benefits * * * outweigh its risk of harm." *Brown & Williamson Tobacco Corp.*, 529 U.S. at 140; see 71 Fed. Reg. 3934 (2006); 60 Fed. Reg. 39,180 (1995); 47 Fed. Reg. 39,149 (1982).

FDA must conduct a robust scientific analysis of a new drug's safety and efficacy, which correspondingly

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[6] FDA's approval of a new-drug application reflects FDA's determination that the drug is safe and effective "under the conditions, prescribed, recommended, or suggested" in its labeling. 21 U.S.C. 355(d). Thus, preemption based on the approval of a drug does not extend to unapproved uses.

entails a substantial commitment of resources by the brand-name manufacturer and follow-on commitments by generic manufacturers. The FDCA requires extensive non-clinical and clinical scientific research to support an NDA. See pp. 2-3, *supra*. FDA approval may be granted only if FDA determines that it has "[ ]sufficient information to determine whether [the] drug is safe" for its labeled uses; concludes that the relevant investigations "include[d] adequate [safety] tests by all methods reasonably applicable"; and finds "substantial evidence" of efficacy, *i.e.*, "adequate and well-controlled investigations" by scientific experts "on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have." 21 U.S.C. 355(d), (d)(1) and (4).

FDA's "rigorous evaluation process" is executed by an "FDA review team—medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts"—which determines whether the "drug is safe and effective for its proposed use" by "scrutiniz[ing] everything about the drug—from the design of clinical trials to the severity of side effects to the conditions under which the drug is manufactured." FDA, *The FDA's Drug Review Process* (May 1, 2012), http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm. FDA may consult with independent panels of scientific experts, 21 U.S.C. 355(n), and "usually communicates often with sponsors about scientific, medical, and procedural issues that arise during the review process." FDA, *The CDER Handbook* 24 (1998) http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM198415.pdf; see 21 C.F.R. 314.50(f)(4), 314.102(a), (c), (d), and (e).

If FDA finds a drug safe and effective, the subsequent ANDA process for generic-drug approval builds upon FDA's determination of the safety and efficacy of the brand-name counterpart. 21 U.S.C. 355(j)(2)(A)(ii)-(iv); see pp. 3-4, *supra*. That ANDA process is designed to ensure that each generic drug is "therapeutically equivalent" to a drug that has passed FDA's rigorous examination and therefore is itself considered to be safe and effective. See p. 4, *supra*.

Congress has further charged FDA with monitoring post-marketing drug safety. A manufacturer must maintain extensive clinical records and make numerous reports to FDA, 21 U.S.C. 355(k)(1), including reports that disclose adverse events associated with the use of its drug, 21 C.F.R. 314.80(a) and (c), 314.81, and all "significant new information * * * that might affect the safety, effectiveness, or labeling of the drug," 21 C.F.R. 314.81(b)(2)(i), (v), and (vi). Those duties apply to manufacturers of generic drugs as well as the brand-name drug. 21 C.F.R. 314.98. In addition, FDA independently receives spontaneous adverse-event reports from health professionals and members of the public. FDA, *Postmarketing Surveillance Programs* (Aug. 19, 2009), http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm090385.htm.

The Act provides that FDA shall withdraw approval of a drug if, *inter alia*, it finds that the drug is not safe for the uses identified at the time of the drug's approval or is not effective as claimed for those uses. 21 U.S.C. 355(e)(1)-(3). Approval may be withdrawn only following procedures that afford the manufacturer due process and the opportunity for a hearing. 21 U.S.C. 355(e).

Since 2007, FDA may also require (not merely request) labeling changes. 21 U.S.C. 355(*o*)(4) (Supp. V 2011).[7]

FDA's ongoing risk-benefit analysis will sometimes take into account the availability of more effective or less risky alternatives, which may change over time. For example, in 2005, when FDA reviewed the risk/benefit profiles of all NSAIDs (p. 7, *supra*), it requested that Bextra be withdrawn from the market because it presented greater safety risks (including of SJS/TEN) than other NSAIDs for the same indication with comparable efficacy. J.A. 560, 579-580 & n.8, 588-591. The manufacturer promptly complied. FDA, *Information for Healthcare Professionals, Valdecoxib (marketed as Bextra)* (July 27, 2010), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124649.htm. But FDA did not request withdrawal of sulindac or other NSAIDs. J.A. 297-298, 364 (explaining that FDA "specifically considered" the research and data on which respondent relies). FDA did withdraw its approval of terfenadine when a safer alternative became available. See 63 Fed. Reg. 53,444 (1998); 62 Fed. Reg. 1889 (1997); cf. 47 Fed. Reg. 22,547-22,548 (1982) (declining to withdraw approval of erythromycin estolate despite lower-risk alternatives because higher risks were "offset by" greater efficacy in certain circumstances).

In the face of this elaborate regulatory regime instituted to safeguard the national market and protect consumers throughout the United States, and the extensive commitment of public and private resources to those

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[7] In 2007, Congress also granted additional FDA authority to ensure the ongoing safety of FDA-approved brand-name and generic drugs. See, *e.g.*, 21 U.S.C. 355(k)(3)-(4), (*o*) and (p), 355-1 (Supp. V 2011).

ends, it would be inconsistent with the FDCA to conclude that a manufacturer must abandon a market it has been approved by FDA to enter in order to avoid violating a duty recognized by a jury under state tort law that deems its product unsafe.

2. By requiring a jury independently to balance the health risks and benefits of FDA-approved uses of a drug and to determine if the drug is "unreasonably dangerous" for those uses, a State with a pure design-defect product-liability law would force the jury to "second-guess[]" FDA's safety determination (Pet. App. 10a), which balances the drug's therapeutic risks and benefits for its labeled uses. Such ad-hoc reconsiderations on a State-by-State and lawsuit-by-lawsuit basis would undermine FDA's drug-safety determinations, which are made based on sound scientific judgments by an expert federal agency with appropriate access to pertinent safety data, and the assurance that FDA's approval provides for all participants in the market.

Federal laws establishing merely minimum safety standards do not normally preempt state-law standards because they do not ordinarily render compliance with federal law impossible or frustrate the federal objective of ensuring minimum levels of safety. See, *e.g.*, *Sprietsma*, 537 U.S. at 57 n.6, 64-68. But where federal regulation is designed to strike a balance between competing considerations, state laws that interfere with the federal balance are impliedly preempted. *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989); *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 321, 326-327, 330 (1981). In *Geier*, for example, an agency determined that public safety was best served by affording manufacturers the choice to install a variety of different passive restraint systems in

their vehicles. 529 U.S. at 874-875, 881. A state suit seeking to impose liability for a manufacturer's decision not to use a particular type of restraint system thus stood as an obstacle to the federal agency's decision. *Id.* at 881-883; see also, *e.g.*, *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 494 (1987) (state nuisance law preempted because it would "upset[] the balance of public and private interests so carefully addressed by" the federal permitting regime for water pollution).

Moreover, state tort liability is "designed to be[] a potent method of governing conduct and controlling policy," *Riegel*, 552 U.S. at 324 (citation omitted), and that very potency can be at odds with FDA's approval of a drug for the interstate market. Tort judgments that second-guess FDA's expert determination have the potential to materially increase a drug's price and/or cause its withdrawal, depriving individuals of access to a drug that FDA has determined is safe and effective for sale in the national market under the approved conditions for use. As this Court recognized in *Reigel*, a jury tends to focus on the risk of a particular design that arguably contributed to a particular plaintiff's injury, not the design's overall benefits, because "the patients who reaped those benefits are not represented in court." *Id.* at 325. FDA, by contrast, has access to extensive safety data and employs scientific experts who impartially analyze drugs' health risks and benefits. That federal regulatory function accounts "for those who would suffer without new [drugs] if juries were allowed" to determine whether a drug was "unreasonably unsafe" under "the tort law of 50 States," *id.* at 326.

In this case, for example, the district court instructed the jury to give FDA's determinations whatever weight it thought appropriate (see p. 10, *supra*), and respond-

ent relied on the *absence* of evidence in the record before the jury indicating whether FDA was aware of data on sulindac's relative safety risks. 9/2/2010 p.m. Tr. 107-108; cf. J.A. 366. But in fact the underlying data came from FDA, and FDA had considered the relevant publication addressing spontaneous reporting rates of SJS/TEN for NSAIDs on which respondent principally rested her design-defect claim. J.A. 297-298, 364; Pet. App. 42a. Indeed, FDA in 2005 conducted a "comprehensive review" of the risks and benefits of all NSAIDs but did not conclude that sulindac or other NSAIDs (aside from Bextra) should be withdrawn from the market based on incidents of SJS/TEN. J.A. 364; cf. Pet. App. 47a n.12 (noting that Bextra had 189 spontaneous adverse-event reports of SJS/TEN in a short, 3.5-year period).

3. As the foregoing discussion shows, brand-name and generic drugs should be treated the same for purposes of design-defect claims. A manufacturer must submit an ANDA and obtain FDA approval before marketing a generic drug. As the court of appeals correctly recognized, the active ingredient in a generic drug must be the same as that in the brand-name drug. Pet. App. 10a. The generic manufacturer may not alter that ingredient without prior FDA approval. See pp. 4-5, *supra*.[8] But the same is true of the manufacturer of a brand-name drug. For both, any change that created a new active ingredient would require prior FDA approval of a new NDA for the resulting new drug product. See pp. 4-5, *supra*.

In light of the statutory purpose of the Hatch-Waxman Amendments to accelerate the availability of

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[8] This case does not involve allegations or evidence regarding the dangerousness or usefulness of any of the inactive ingredients of petitioner's sulindac.

low-cost generic alternatives to brand-name drugs, see *House Report* 14-15, preemption in the generic-drug context, just as in the brand-name-drug context, should not be defeated on the rationale that the manufacturer could always comply with state law by declining to provide the very drug whose availability Congress sought to provide in generic form to the public. In both situations, a state-law design-defect claim would lie only if it rested on new, scientifically significant information that rendered the drug misbranded.

4. The court of appeals supported its contrary conclusion by reading *Wyeth* as "adopt[ing] a general no-preemption rule" logically covering all drug-design-defect claims. Pet. App. 11a. That reading is incorrect. "[G]eneral expressions, in every opinion, are to be taken in connection with the case in which those expressions are used," *Cohens* v. *Virginia*, 19 U.S. (6 Wheat.) 264, 399 (1821) (Marshall, C.J.), and the passages in *Wyeth* must be read in context.

The passages in *Wyeth* on which the court of appeals relied were in Part IV of the Court's opinion addressing obstacle preemption. Pet. App. 9a (quoting 555 U.S. at 574-575, 578). By that point, the Court, in Part III of its opinion, had already rejected impossibility preemption on the ground that FDA's CBE regulation affirmatively authorized a manufacturer to change the labeling unilaterally, subject only to later FDA review. It is not surprising in that context that the Court rejected the manufacturer's further contention that the Act's purposes would be frustrated by subjecting to liability under state law a brand-name-drug manufacturer that had newly acquired information undermining its drug's safety but that failed to strengthen its labeling as specifically contemplated by FDA's CBE regulation.

In rejecting obstacle preemption, the Court observed that Congress's failure to enact an express preemption provision for prescription drugs, as it had done for medical devices in 1976 (see 555 U.S. at 567)—when combined with Congress's "certain awareness of the prevalence of state court litigation"—indicated that Congress would not have believed such "state-law suits posed an obstacle to its objectives," or that "FDA oversight [was] the exclusive means of ensuring drug safety and effectiveness." *Id.* at 574-575. *Wyeth* accordingly declined to accept the view that FDA's labeling approvals, and the mere possibility that FDA would disapprove a manufacturer's subsequent enhanced warning on safety grounds under the CBE regulation, necessarily preempt a state-law failure-to-warn suit when the manufacturer did not make such a change, because the government failed in that situation to explain "how state law has interfered with FDA's regulation of drug labeling during decades of coexistence." *Id.* at 577.

That analysis does not categorically extend to all claims that the design of a drug's active ingredient is defective, because a manufacturer cannot unilaterally alter the design (unlike the labeling) of a drug. A defective-design claim would lie only if based on significant new evidence that triggered a duty under federal law not to market a misbranded drug. Significantly, moreover, the Court in *Wyeth* rested its preemption ruling in large part on criticism of the preamble to a 2006 FDA labeling rule for what the Court regarded as the novel proposition that when FDA approves an NDA that includes particular labeling, it must be presumed to have performed a precise balancing of risks and benefits with respect to labeling and established a specific labeling standard that leaves no room for different state-law

judgments. See 555 U.S. 575-581. In this case, by contrast, the proposition that FDA's approval of a drug as safe and effective does reflect an expert judgment that the drug's therapeutic benefits outweigh its risks for the uses identified in the labeling is based on FDA's longstanding interpretation of the Act, affirmed by this Court in *Brown & Williamson Tobacco Corp.*, 529 U.S. at 140, and *Rutherford*, 442 U.S. at 555.

It is also instructive that *Wyeth* supported its view that tort suits "continued unabated despite . . . FDA regulation" by citing the decisions collected at footnote 11 in Justice Ginsburg's dissenting opinion in *Riegel*, 552 U.S. at 340 n.11. See *Wyeth*, 555 U.S. at 567. Those decisions primarily involved failure-to-warn claims; and the four that addressed attempts to extend general product-liability design-defect principles to prescription drugs did not deem the drugs' designs defective per se, but rather conditioned recovery on proof of inadequate warnings.[9] That pattern reflects that courts "traditional[ly] refus[ed]" to "impose tort liability for defective designs of prescription drugs" and allowed liability "only" for "manufacturing defects" and "[in]adequate instructions and warnings." *Third Restatement* § 6 cmts. a and b, at 145-146; Pet. App. 5a. Although some courts in the 1980s began to recognize pure design-defect claims for prescription drugs without labeling deficiencies, such strict-liability claims continued to be unusual: As of the late 1990s, it was "relatively rare" for

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[9] See *Reyes* v. *Wyeth Labs.*, 498 F.2d 1264, 1273-1275 (5th Cir.) (Texas law), cert. denied, 419 U.S. 1096 (1974); *Basko* v. *Sterling Drug, Inc.*, 416 F.2d 417, 425-426 (2d Cir. 1969) (Connecticut law); *Davis* v. *Wyeth Labs., Inc.*, 399 F.2d 121, 126-129 (9th Cir. 1968) (Montana law); *Cunningham* v. *Charles Pfizer & Co.*, 532 P.2d 1377, 1380-1381 (Okla. 1974).

FDA-approved drugs to be held defectively designed. Robert B. Leflar & Robert S. Adler, *The Preemption Pentad*, 64 Tenn. L. Rev. 691, 715 & n.128 (1997); see James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the* Restatement (Second) of Torts, 77 Cornell L. Rev. 1512, 1537 n.40 (1992) (1981 decision "is widely believed to be the first case directly raising a defective drug design claim").

For these reasons, *Wyeth*'s conclusion that "Congress did not intend FDA oversight" to preempt state tort litigation reflects that *certain* state-law claims traditionally have been understood as "a complementary form of drug regulation." 555 U.S. at 575, 578. *Wyeth* thus "recognize[d] that some state-law claims might well frustrate the achievement of congressional objectives" even as it concluded that the failure-to-warn action before it was "not such a case." *Id.* at 581 (emphasis added). By contrast, federal law would preempt a pure defective-drug-design claim that required a jury to second-guess FDA's safety determination, without any further need to find the existence of new and scientifically significant evidence that rendered the product misbranded under federal law.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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AMICUS CURIAE BRIEF

RECORD
AND
BRIEFS

NO. 12-142

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IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,

Petitioner,

v.

KAREN L. BARTLETT,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

AMICI CURIAE BRIEF OF THE AMERICAN ASSOCIATION FOR JUSTICE AND PUBLIC JUSTICE IN SUPPORT OF RESPONDENT

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INTERESTS OF *AMICI CURIAE*[1]

The American Association for Justice ("AAJ") and Public Justice submit this brief as amici curiae in support of Respondent Karen L. Bartlett.

AAJ is a voluntary national bar association whose trial-lawyer members primarily represent individual plaintiffs in civil suits, including personal injury actions, consumer lawsuits, and employment-related cases. Many AAJ-member attorneys represent consumers who have been harmed by dangerous prescription drugs, including consumers who live in New Hampshire. AAJ believes that holding drug makers accountable justly compensates those they have harmed and provides drug companies with a strong incentive to minimize the risk of harm to consumers.

AAJ has also appeared as an amicus curiae in litigation concerning whether federal regulation of prescription drugs and medical devices preempts traditional state-law causes of action. AAJ believes that state tort litigation generally complements and furthers the purposes of the federal regulatory scheme and, therefore, that few state tort claims should be held to be preempted by federal law.

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[1] Pursuant to Supreme Court Rule 37.6, amici state that no counsel for a party authored any part of this brief, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae, its members, or its counsel made a monetary contribution to the brief's preparation or submission. The parties' blanket consents to the filing of amicus curiae briefs are on file with the Clerk.

Public Justice is a national public interest law firm dedicated to pursuing justice for victims of corporate and government wrongdoing. Through involvement in precedent-setting and socially significant litigation, Public Justice seeks to ensure that tort law compensates those injured by wrongful conduct and deters similar conduct in the future. As part of its work, Public Justice has represented consumers injured by prescription drugs and litigated many tort cases involving preemption defenses, including as co-counsel for Gladys Mensing in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Public Justice is concerned that if tort remedies against generic drug manufacturers are limited through improper application of preemption principles, injured patients will be left without compensation and generic manufacturers will not have adequate incentive to ensure that their drugs are safe.

INTRODUCTION AND SUMMARY OF ARGUMENT

Petitioner Mutual Pharmaceutical Company, Inc., a generic manufacturer of a non-steroidal anti-inflammatory drug (NSAID) with the nonproprietary name sulindac, seeks a ruling that Congress, in enacting and amending the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, intended to deprive injured parties like Respondent of longstanding compensation for defective drugs.[2]

Congress has not expressly preempted state tort actions against prescription drug manufacturers, even as it has periodically enlarged the Food and Drug Administration's (FDA's) power to administer federal law. *See Wyeth v. Levine*, 555 U.S. 555, 566-67 (2009). Petitioner argues, however, that preemption may be inferred because it is "impossible" for drug manufacturers to comply with both state law and federal law; and because state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" as expressed in the FDCA. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-373 (2000).

The question is ultimately one of congressional intent. When "'Congress has legislated . . . in a field which the States have traditionally occupied, . . . [courts] start with the assumption that the historic police powers of the States were not to be superseded

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[2] These amendments include the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Sept. 24, 1984), known commonly as the Hatch-Waxman Act.

by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Levine*, 555 U.S. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); some internal quotation marks omitted). That is particularly true as to matters of health and safety, which traditionally are areas of State concern. *Lohr*, 518 U.S. at 485. The presumption against preemption has added force in this context. *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985).

Strictly as a matter of impossibility preemption, there is no basis to infer a conflict. Nothing in federal law prohibits a drug manufacturer from complying with a state-law judgment obligating it to pay compensation to a patient injured by a drug found to be unreasonably dangerous on the record in the case. Indeed, federal law does not even require a manufacturer, whether brand-name or generic, to sell a non-life-saving drug that has met FDA approval. *See* 21 U.S.C. § 356c; 21 C.F.R. § 314.161. Federal law permits both brand-name and generic manufacturers independently to stop selling a drug. *See id.*

As for obstacle preemption, Petitioner has not preserved that affirmative defense for this Court's review. *See* Resp't Br. 39-40. Had it been properly preserved, however, the argument would nonetheless fail on the merits. State-law liability based on significant new evidence that a drug is unreasonably dangerous if taken for its approved uses *parallels* the federal-law duty not to market a misbranded drug. In this circumstance, state law complements federal law's purposes and objectives.

The United States' discussion of conflict preemption in a hypothetical case concerning what it calls a "pure" design-defect claim contains two significant errors. First, the United States' account of post-marketing regulation fails either to acknowledge the agency's shortcomings, which hamper its ability to monitor the safety and efficacy of prescription drugs, or to credit product-liability litigation for providing a critical layer of consumer protection. The *Levine* Court made no such mistake. It recognized that the FDA lacks the resources to monitor the safety profiles of the more than 11,000 drugs on the market; and that the FDA is a largely reactive institution that depends on the press, manufacturers, *and* litigation to uncover safety hazards. *See* 555 U.S. at 578-79 & n.11.

Second, the United States errs in suggesting that an injured plaintiff must "prove that the manufacturer knew or should have known of new and scientifically significant evidence that rendered the drug 'misbranded' under federal law"; or that States must rewrite their tort laws accordingly. U.S. Br. 12, 16 & n.3. If the FDCA, by operation of the Supremacy Clause, is read to displace design-defect claims absent such evidence, then such evidence will be required only as a consequence of preemption. Because the burden of establishing the affirmative defense of preemption rests with the defendant, the defendant manufacturer should be required to prove that all of plaintiff's evidence of defect had already been considered by the FDA and had been found insufficient to render a drug misbranded. Further, the States need not rewrite their tort laws to accommodate possible preemption defenses. The Supremacy Clause displaces contrary state law, but it does not require any affirmative action by the

States. The United States' contrary suggestion fails to appreciate this feature of our federalism.

ARGUMENT

CONGRESS DID NOT INTEND TO DEPRIVE PERSONS INJURED BY UNREASONABLY DANGEROUS DRUGS OF LONG AVAILABLE COMPENSATION.

A. Even a State-Law Prohibition Against the Sale of a Particular, Unreasonably Dangerous Drug Would Not Pose an Impossibility Conflict with Federal Law When Federal Law Does Not Require Drug Manufacturers to Sell Drug Products.

1. In order to show 'impossibility,' a defendant must prove that "compliance with both federal and state [law] is a physical impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). Such 'impossibility' can only exist when two statutes impose "directly conflicting duties"—"as they would, for example, if the federal law said, 'you must sell insurance,' while the state law said, 'you may not.'" *Barnett Bank of Marion Cnty., NA v. Nelson*, 517 U.S. 25, 31 (1996). But "physical impossibility" does not exist where state law merely authorizes an action that federal law forbids. *Michigan Canners & Freezers Ass'n, Inc. v. Agricultural Marketing & Bargaining Bd.*, 467 U.S. 461, 478 n.21 (1984) ("Because the Michigan Act is cast in permissive rather than mandatory terms—an association may, but need not, act as exclusive bargaining representative—this is not a case in

which it is impossible for an individual to comply with both state and federal law.").

Petitioner cannot make that demanding showing here. It cannot show that state law *requires* anything that federal law *forbids*, or vice-versa—the only circumstances in which compliance with state and federal law is physically impossible. *See Barnett Bank*, 517 U.S. at 31; *Michigan Canners*, 467 U.S. at 478 n.21

The district court in this case concluded that New Hampshire's "strict products liability requires[]" "that manufacturers compensate consumers for the damage caused by unreasonably dangerous products, not necessarily that they remove such products from the market." 2010 WL 3092649, at *8 (D. N.H. Aug. 2, 2010) (JA 305) (citing 5 Louis R. Frumer & Melvin I. Friedman, *Products Liability* § 57.01[4], at 57-9 (2010) for the proposition that "almost all of the opinions which have addressed the issue have found that there is no common law duty to recall or retrofit" unreasonably dangerous products)). The court of appeals' decision, though not explicit on this point, at least implicitly endorsed the district court's understanding that New Hampshire design-defect liability obligates a defendant to pay damages. *See* Pet. App. 10a-11a (noting that "the decision [of a manufacturer] to make the drug and market it is wholly its own").

A state-law obligation to compensate injured parties, standing alone, does not "directly" conflict with any FDCA requirement. Federal law does not forbid the payment of compensatory damages; therefore, it is not physically impossible to comply with both state and federal law. *See Barnett Bank*,

517 U.S. at 31; *Michigan Canners*, 467 U.S. at 478 n.21. This remains true even if the payment of damages once, twice, or even multiple times might induce a manufacturer to stop selling its product; "[a]n occurrence that merely motivates an optional decision does not qualify as a requirement." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005).

Even assuming for argument's sake that a design-defect claim were premised on the violation of an underlying duty not to sell an unreasonably dangerous drug, however, it still would not be physically impossible for a manufacturer to comply with both state law and federal law. This is because federal law expressly *permits* both brand-name and generic manufacturers to stop selling a non-life-saving drug. *See* 21 U.S.C. § 356c; 21 C.F.R. § 314.161.[3] That decision, moreover, is one that manufacturers can make independently of the FDA, *see id.*—in other words, "unilaterally," *see Mensing*, 131 S. Ct. at 2581. And it is one manufacturers make with some frequency; "studies show[] that anywhere from one-third to one-half of generic drugs no longer have a marketed brand-name equivalent." *Id.* at 2584 (Sotomayor, J., dissenting) (citing Brief for Marc T. Law, *et al.* as Amici Curiae 18).[4] Thus, even if this Court understood state law to be saying, "You

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[3] But where a drug company "is the sole manufacturer of a drug that is life-supporting; life-sustaining; or intended for use in the prevention of a debilitating disease or condition," federal law may require the company to give the FDA six months notice of its intent to discontinue selling the drug. 21 U.S.C. § 356c. Sulindac is not such a drug.

[4] As described below, where a drug is believed to be misbranded, it is common practice that a manufacturer is allowed to withdraw its product from the market voluntarily.

must stop selling your drug," federal law does not say, "You must sell your drug." It says only: "You *may* sell your drug." Under *Michigan Canners*, this is insufficient to establish physical impossibility. *See* 467 U.S. at 478 n.21 (in case where state law was permissive and federal law mandatory, compliance with federal and state law was not physically impossible).

2. Petitioner takes a decidedly different view of state and federal law. A manufacturer can only avoid liability for design defect, Petitioner argues, by redesigning its drug. That obligation, Petitioner maintains, conflicts with federal law, which does not permit a manufacturer to do so unilaterally; and in any event, a redesign is impossible here because sulindac is a one-molecule drug. Pet'r's Br. 30-36.

The impossibility conflict Petitioner describes is premised on a misunderstanding of design-defect law. Design-defect liability does not turn on the capacity to redesign a drug. Neither distributors nor retailers have control over the design of the product, yet both have been held liable for defective design. *See Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528 (6th Cir. 1993) (distributor; applying Kentucky law); Restatement (Second) of Torts § 402A cmt. f (1965) ("The rule stated in this Section applies to any person engaged in the business of selling products for use or consumption. It therefore applies to any manufacturer of such a product, to any wholesale or retail dealer or distributor, . . .").[5] This establishes

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[5] *See also* Robert A. Sachs, *Product Liability Reform and Seller Liability: A Proposal For Change*, 55 Baylor L. Rev. 1031, 1032-33 (2003) ("Under the common law in almost all states, all sellers in the chain of distribution of a product are strictly liable for defects found in that product. It does not

that the power to redesign a product is not an element of the cause of action. It is not impossible, then, to comply with both federal law, which does not permit a manufacturer to unilaterally alter a drug's design, and state law, which extends liability to a manufacturer of a defectively designed drug without regard to whether it may redesign its drug. Because state law does not require what federal law forbids, there is no impossibility conflict here.

3. Petitioner and the United States suggest that *Mensing* and *Levine* foreclose the argument that state-law design-defect claims do not conflict with federal law because a manufacturer is not required to make its drug. A close reading of these cases suggests, however, that the Court did not examine this argument.

Consider first *Mensing*: The injured plaintiff in that case did not argue that the manufacturer there "could not show impossibility because federal law merely permitted them to sell generic drugs; it did not require them to do so." 131 S. Ct. at 2588 n.8 (Sotomayor, J., dissenting). Accordingly, neither the majority nor the dissent in *Mensing* considered the argument. Instead, the majority's holding rested on its understanding that federal law did not permit a unilateral labeling change, but that state law required a labeling change. *See id.* at 2573 (noting that this understanding of state law was "undisputed"). This clash of mandatory duties—*must*

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matter if the seller is a wholesaler or retailer who had no part in the creation of the defect, no control over the product's manufacture or design, or no reason to believe the product was defective.").

and *must not*—does not exist here, for the reasons just discussed.

Consider next *Levine*: The Court in that case did not have occasion to consider the stop-selling argument outlined here. In *Levine*, the Court concluded, in view of the record before it, that the brand-name manufacturer in that case had failed to establish, by clear evidence, that the FDA would not have approved a labeling change. 555 U.S. at 572-73. It therefore was not impossible for the manufacturer to comply with both federal labeling requirements and any state-law obligation to provide adequate warnings of health risks. *Id.* Given this conclusion, there was no reason for the *Levine* Court to consider any alternative argument against impossibility preemption, and none was advanced. *See id.*

* * *

Impossibility preemption is a demanding defense because "respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly pre-empt state-law causes of action.'" *Levine*, 555 U.S. at 565-66, n.3 (quoting *Lohr*, 518 U.S. at 485); *see generally, Nw. Cent. Pipeline Corp. v. State Corp. Comm'n*, 489 U.S. 493, 515 (1989) ("conflict-pre-emption analysis must be applied sensitively in this area, so as to prevent the diminution of the role Congress reserved to the States while at the same time preserving the federal role"). Its demands should be particularly weighty here, given the longstanding co-existence of state tort liability and federal drug-safety law; and given that preemption would leave injured persons such as Respondent without a remedy. *Bruesewitz v. Wyeth LLC*, 131 S.

Ct. 1068, 1080 (2011) (recognizing the Court's longstanding "doubt that Congress would quietly preempt product-liability claims without providing a federal substitute").

Petitioner cannot satisfy this stringent test in this case. As discussed, it can readily comply with both state and federal law obligations, and it may do so unilaterally, meaning, "without the Federal Government's special permission and assistance." *Mensing*, 131 S. Ct. at 2581. Petitioner's belief that it was the clear and manifest purpose of Congress to wipe out longstanding product-liability suits for defective design therefore cannot be credited.

B. Design-Defect Claims Based on Significant New Evidence That a Drug Is Unreasonably Dangerous Complement the Purposes and Objectives of the FDCA.

Petitioner argues that design-defect liability stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, as expressed in the FDCA. But as Respondent demonstrates, Petitioner failed to preserve that argument for this Court's review. Resp't Br. 39-40.

Even had it been preserved, however, Petitioner's obstacle preemption argument would fail on the merits. State-law liability based on significant new evidence that a drug is unreasonably dangerous if taken for its approved uses *parallels* the federal-law duty not to market a misbranded drug. That federal duty is "triggered" (U.S. Br. 32) where there is significant new evidence that a drug is dangerous to health if taken in a manner consistent with its

labeling. *See* 21 U.S.C. § 352(j). In these circumstances, state tort law complements the purposes and objectives of the FDCA.

1. This conclusion follows from the structure and purpose of federal law. Congress, in enacting and amending the FDCA, intended for drug manufacturers like Petitioner—not the FDA—to maintain front-line responsibility for drug safety "at all times." *See Levine*, 555 U.S. at 570-71 ("[T]hrough many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."). This responsibility extends to all prescription drug manufacturers, whether brand-name or generic. *See* U.S. Br. 5 (noting that new drug applicants for brand-name drugs and abbreviated new drug applicants for generic versions of brand-name drugs must "promptly report to FDA serious adverse events associated with use of its drug in humans and periodically submit certain new information that may affect FDA's previous conclusions about the drug's safety or effectiveness").

The structure and purpose of the FDCA and its animating regulations also demonstrate that FDA approval of a drug is not intended to "represent a singular moment of clarity about risks and benefits associated with a drug." Inst. of Med. of the Nat'l Acads., *The Future of Drug Safety, Promoting and Protecting the Health of the Public* 27 (2007); *see Levine*, 555 U.S. at 575 (rejecting the argument that, although "the FDCA requires the FDA to determine that a drug is safe and effective under the conditions set forth in its labeling, the agency must be presumed to have performed a precise balancing of

risks and benefits and to have established a specific labeling standard that leaves no room for different state-law judgments"); *see id.* at 592 (Thomas, J., concurring in the judgment) (FDA approval "does not represent a finding that the drug, as labeled, can never be deemed unsafe by later federal action, or as in this case, the application of state law.").[6] Risks and benefits emerge over time as a drug is introduced into the population; accordingly, "[a]ll consumers of prescription drugs serve as guinea pigs for the pharmaceutical industry." Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 20 (1973). It is only after a drug is widely sold that "risks that are relatively rare, that manifest themselves only after an extended period of time, or that affect vulnerable subpopulations, begin to emerge." David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts To Preempt Failure-To-Warn Claims*, 96 Geo. L.J. 461, 466 (2008).

The FDA monitors these risks, but not by itself. "[S]tate law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Levine*, 555 U.S. at 579. This added layer of consumer protection is essential:

> The FDA has limited resources to monitor the 11,000 drugs on the

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[6] *See also* Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 Yale J. Health Pol'y L. & Ethics 587, 598 (2005) ("Even if it is rigorously conducted, a process that focuses on prior approval inevitably will fail to capture all relevant information.").

> market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information.

Id. at 578-79.

2. The United States considers at length whether a hypothetical suit alleging what it calls a "pure" design-defect claim would conflict with the FDCA. This discussion fails to appreciate the FDA's limitations or state tort law's consumer-protection role. And it suggests (erroneously) that conflict preemption principles here require States to rewrite their tort laws to place new burdens of proof on injured plaintiffs—even though preemption is an affirmative defense which defendant manufacturers must establish.

a. The United States' account of the FDA's role in monitoring the safety profiles of drugs is deficient because it fails to acknowledge the agency's serious shortcomings in post-market regulation. *See* U.S. Br. 24-28. "The agency's powers and resources in new drug review, however inadequately they are perceived by some critics, appear cosmic when contrasted with the tools available for post-market regulation." Daniel Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA* 586 (Princeton Univ. Press

2010) (hereinafter Carpenter). In *this* area, the FDA's "weaknesses are glaring and are the subject of extensive study and lament in contemporary medicine and politics." *Id.*

Three recent, independent studies of the FDA, cited by the Court in *Levine*, exposed these glaring weaknesses. FDA Science Board, *Report of the Subcommittee on Science and Technology: FDA Science and Mission at Risk* 2, 6 (2007) ("[T]he Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities"); Inst. of Med. of the Nat'l Acads., *The Future of Drug Safety: Promoting and Protecting the Health of the Public* 193-94 (2007) ("The [FDA] lacks the resources needed to accomplish its large and complex mission. . . . There is widespread agreement that resources for postmarketing drug safety work are especially inadequate and that resource limitations have hobbled the agency's ability to improve and expand this essential component of its mission"); GAO, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process* 5 (GAO-06-402, 2006) ("FDA lacks a clear and effective process for making decisions about, and providing management oversight of, postmarket safety issues"), *cited approvingly in* 555 U.S. at 578-79 n.11.

The United States ignores this aspect of *Levine*, and does not engage these studies. But they remain highly relevant. More recent reporting, moreover, only reinforces their central conclusion: The FDA is incapable of carrying out its mission. As reported by Marcia Angell, a former editor-in-chief of The New England Journal of Medicine,

> [T]here is growing evidence that the Center for Drug Evaluation and Research (CDER, pronounced "cedar"), the part of the agency that regulates prescription drugs, has become the servant of the industry it regulates. This has resulted in the sale of drugs of uncertain benefits, some with serious side effects, and in the agency's failure to respond promptly to evidence that a drug is dangerous.

Marcia Angell, *FDA: This Agency Can Be Dangerous*, N.Y. Review of Books, Sept. 30, 2010, at 66 (hereinafter Angell).[7]

Angell describes the FDA's 2005 review of the COX-2 inhibitor Bextra, which the United States now suggests also included a review of all NSAIDs (including sulindac), *see* U.S. Br. 24. She lays bare conflicts of interest and deficiencies in the review process that the United States' account ignores. For example, Angell writes that a special FDA panel, consisting of two standing advisory committees, was convened to consider whether Vioxx, Bextra, and Celebrex were safe enough to remain on the market. The panel recommended that all three drugs remain on the market "perhaps with strong warnings on the labels and a moratorium on advertising directly to consumers." Angell, at 67.

> About a week later, however, *The New York Times* revealed that ten of the thirty-two members of the panel had

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[7] *Available at* http://www.nybooks.com/articles/archives/2010/sep/30/agency-can-be-dangerous/?pagination=false.

> financial ties to the makers of the drugs. If their votes had been discounted, the panel would have recommended that only Celebrex stay on the market. In a departure from its usual practice, CDER, no doubt embarrassed, rejected the advice of the full panel and allowed only Celebrex to stay on the market. If not for the revelations in *The New York Times*, the decision would probably have gone the other way.

Id.

According to Daniel Carpenter, of Harvard University, there exists also a structural "conflict of interest" in the FDA's post-market review process: "The very office of the FDA that approves new drugs—and which therefore has the least reputation-based incentives to revisit its past approval decisions—is also the office with legal authority over post-marketing." Carpenter, at 630. FDA officials have echoed this concern. *Id.* (quoting Office of Drug Safety epidemiologist David Graham as stating in testimony before Congress that "the new drug reviewing division that approved the drug in the first place and that regards it as its own child, typically proves to be the single greatest obstacle to effectively dealing with serious drug safety issues").

b. The United States also fails to credit product-liability litigation for providing a critical layer of consumer protection.

As already noted, state tort law complements federal law in two important ways: It serves a

remedial function, and it plays a critical role in uncovering unknown drug hazards and providing incentives for drug manufacturers to disclose safety risks promptly. *Levine*, 555 U.S. at 578-79.[8]

Some examples: There have been substantial delays between the time drug manufacturers had "reasonable evidence of an association of a serious hazard" with certain drugs, 21 C.F.R. §§ 201.57(c)(6)(i), 201.80(e), and when they either provided that information to the FDA; warned physicians and patients of emerging risks; or voluntarily withdrew the drug from the market. This has happened with Vioxx,[9] Celebrex,[10] Propulsid,[11]

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[8] Congress, in 2007, enhanced the FDA's regulatory authority and provided it with additional resources to monitor drug safety. *See* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007). These amendments "reaffirmed" that front-line responsibility for drug safety rests with manufacturers. *Levine*, 555 U.S. at 571. But FDA's resources remain limited. *See* Angell, at 67 (noting that staffing for drug approval far exceeds staffing for drug safety); *see also* FDA, Update from the Office of Surveillance and Epidemiology, p. 5 (Dec. 10, 2012) (8 year staffing totals).

[9] *McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 241-44 (N.J. Super Ct. App. Div. 2008) (noting Merck's delays in reporting information about Vioxx's cardiovascular risks to FDA).

[10] Alex Berenson & Gardiner Harris, *Pfizer Says 1999 Trials Revealed Risks With Celebrex*, N.Y. Times, Feb. 1, 2005, at A1 (reporting that Pfizer acknowledged withholding from FDA for two years study showing serious cardiovascular risk with Celebrex), *available at* http://www.nytimes.com/2005/02/01/business/01drug.html.

[11] Gardiner Harris & Eric Koli, *Lucrative Drug, Danger Signals and the FDA*, N.Y. Times, June 10, 2005 (reporting that Johnson & Johnson delayed in submitting safety information on heartburn medication Propulsid to FDA), *available at*

Rezulin,[12] Darvon,[13] and Bextra.[14] State tort litigation was instrumental in uncovering these hazards, or in providing a fuller understanding of the manufacturers' conduct. Also, state tort law has provided (and may yet provide) critical compensation to the tens of thousands of persons injured by these drugs.

The importance of product-liability law is also evident outside the context of pharmaceutical drugs. For example, the history of so-called blood-shield laws, which foreclosed strict liability and implied warranty causes of action against blood collection centers, illustrates the consequences of foreclosing product-liability claims. States widely enacted such laws on the premise that blood banks were so important that their work should not be hampered by litigation. George C. Conk, *Is There A Design Defect In The Restatement (Third) Of Torts: Product Liability?*, 109 Yale L.J. 1087, 1100 (2000). Shielded from strict liability, the blood banks lacked a key

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http://www.nytimes.com/2005/06/10/business/10drug.html?pagewanted=all&_r=0.

[12] Denise Grady, *FDA Reviews Accusations About Diabetes Drug*, N.Y. Times, Mar. 16, 2000 (reporting that FDA records showed that company failed to submit safety data on diabetes drug Rezulin), *available at* http://www.nytimes.com/2000/03/16/us/fda-reviews-accusationsabout-diabetes-drug.html.

[13] Rob Stein, *Controversial painkiller Darvon pulled at FDA's request*, Washington Post, Nov. 19, 2010, *available at* http://www.washingtonpost.com/wp-dyn/content/story/2010/11/20/ST2010112000477.html.

[14] Stephanie Saul, *Pfizer to Settle Claims Over Bextra and Celebrex*, N.Y. Times, Oct. 17, 2008, *available at* http://www.nytimes.com/2008/10/18/business/18drug.html?_r=0

"incentive to pursue research and development of pasteurization techniques to reduce the risk of contracting hepatitis (and later HIV) from the blood supply. The blood shield laws thus allowed the blood industry to continue to make blood products that were avoidably unsafe, at tremendous cost to human life." *Id.* at 1100.

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Statistics from 2005 to 2008 demonstrate that 47.9 percent of persons in the United States used at least one prescription drug in the last month reported; 21.4 percent used three or more; and 10.5 percent used five or more. Centers for Disease Control and Prevention, FastStats: Therapeutic Drug Use.[15] Given the ubiquity of prescription drugs, and the FDA's limited resources, the public would be at serious risk of harm if the consumer protection provided by the tort system were found to be preempted.

c. Lastly, the United States errs in suggesting that conflict preemption principles require that an injured plaintiff "prove that the manufacturer knew or should have known of new and scientifically significant evidence that rendered the drug 'misbranded' under federal law" (U.S. Br. 12), or that States must now redefine "the scope of [their] tort duties" accordingly (*see* U.S. Br. 16 n.3).[16]

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[15] *Available at* http://www.cdc.gov/nchs/fastats/drugs.htm.

[16] *See* 21 U.S.C. §§ 331(a)-(c), (g), and (k) (prohibiting the production or distribution of any drug that is misbranded); 21 U.S.C. § 352(j) (defining 'misbranded' partly to mean "dangerous to health when used in the dosage or manner, or

State product-liability law already incorporates risk-benefit analysis, *see* Restatement (Second) of Torts § 402A, and juries may consider evidence of FDA approval in reaching a verdict, *e.g.*, *Tobin*, 993 F.2d at 538. If, however, the FDCA, by operation of the Supremacy Clause, were read to displace design-defect claims absent evidence that a drug was misbranded under federal law, then the role of this evidence in product-liability litigation against a drug manufacturer would arise only as a result of the manufacturer's preemption defense. *Cf. Mensing*, 131 S. Ct. at 2588 n.11 (Sotomayor, J., dissenting). Because the burden of establishing a preemption defense rests with defendants, the defendant manufacturer should be required to prove that all of plaintiff's evidence of defect had already been considered by the FDA and had been found insufficient to render a drug misbranded. *See Levine*, 555 U.S. at 571 (requiring defendant manufacturer to show clear evidence that the FDA would not have approved a labeling change).

The United States' suggestion that States must rewrite their tort law (*see* U.S. Br. 16 n.3) misapprehends our federalism. The Supremacy Clause, though it displaces contrary state law, does not require any affirmative action by the States. *Cf. Haywood v. Drown*, 556 U.S. 729, 752 (2009) (Thomas, J., dissenting) ("This historical record makes clear that the Supremacy Clause's exclusive function is to disable state laws that are substantively inconsistent with federal law—not to require state courts to hear federal claims over which the courts lack jurisdiction."). The preemption

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with the frequency or duration prescribed, recommended, or suggested in the labeling thereof").

defense is available whether or not States explicitly anticipate it. *Cf. Bates*, 544 U.S. at 454 (recognizing that it would be "surprising" for state tort law to parallel federal requirements "in *identical* language" but that where some equivalency is required, defendants seeking to rely on preemption may ask for jury instructions on relevant federal standards (emphasis in original)).

CONCLUSION

For the foregoing reasons, the judgment under review should be affirmed.

Feb. 20, 2013 Respectfully submitted,

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AMICUS CURIAE BRIEF

RECORD AND BRIEF

No. 12-142

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IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,

Petitioner,

v.

KAREN L. BARTLETT,

Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

ROBIN S. CONRAD
SHELDON GILBERT
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BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. The Chamber represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry, from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of vital concern to the Nation's business community.

The Pharmaceutical Research and Manufacturers of America (PHRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies research, develop, and manufacture

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[1]The parties' consent to the filing of *amicus* briefs has been filed with the Clerk. Under Rule 37.6 of the Rules of this Court, *amici curiae* state that no counsel for a party has authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than *amici curiae*, their members, or their counsel, has made a monetary contribution to this brief's preparation or submission.

medicines that allow patients to live longer, healthier, and more productive lives. In 2011 alone, PhRMA member companies invested an estimated $49.5 billion to discover and develop new medicines. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates as an *amicus curiae* in cases before this Court.

The free flow of commerce within the United States is at the heart of the Founders' vision of our federal union. The movement of goods and services across state boundaries, unimpeded by parochial state interests, is essential to a strong national economy, job creation, and consumer welfare. The First Circuit's decision condoned individual state determinations that the shipment of nationally distributed and federally regulated prescription drugs into a state could be a wrongful act for which tort liability can be imposed on the drug manufacturer. That holding not only would isolate physicians and their patients within the affected state but also would have extraterritorial effects on the national drug distribution system. The First Circuit's decision is particularly egregious because it sustains a jury determination that a risk-benefit balance should have precluded Petitioner Mutual Pharmaceutical Company, Inc. (Mutual) from selling its sulindac drug in New Hampshire – even though the federal agency congressionally mandated to determine that *same* balance reached the *opposite* conclusion when authorizing Mutual to engage in interstate shipment of sulindac. Moreover, the First Circuit's "stop selling" theory, if adopted in other contexts, threatens to eviscerate the federal preemption defense that is essential to promoting the

free flow of federally regulated goods in numerous sectors of the economy. Because the decision below jeopardizes the public health, threatens to contribute to further balkanization of the national economy, and conflicts with the Supremacy Clause, the Commerce Clause, and the precedents of this Court, *amici* respectfully urge that it be reversed.

SUMMARY OF ARGUMENT

The judgment in this case should be reversed because the state law tort claim on which it is founded is preempted under federal law. The jury's determination that Mutual's sulindac formulation has a design defect under state law, based on the jury's own risk-benefit analysis, is irreconcilable with the expert determination by the United States Food and Drug Administration (FDA) that sulindac is safe and effective and should be available as a matter of federal law to prescribing physicians and their patients. The First Circuit's remarkable conclusion that Mutual could comply with its federal license to make and sell sulindac nationwide *and* its state law duty not to do so by "choos[ing] not to make the drug at all," *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 37 (1st Cir. 2012), is contrary to this Court's recent decision in *PLIVA, Inc. v. Mensing*, ___ U.S. ___, 131 S. Ct. 2567 (2011), and would effectively eviscerate much of this Court's preemption jurisprudence.

The judgment also should be reversed because it is antithetical to important Commerce Clause principles. Fostering the free flow of goods in a national market was a central goal of the Founders in adopting the Constitution; that goal consistently has been reflected in this Court's jurisprudence, even recognizing that

states have certain regulatory powers within their own borders. This Court repeatedly has rejected state attempts – legislative or judicial – to isolate a state from the national stream of commerce or to extend the effects of its regulation beyond its borders. As articulated by the First Circuit, the judgment at issue would do precisely that, by allowing a determination by a New Hampshire jury effectively to supersede FDA's expert determination that sulindac should be available on a nationwide basis. Such an approach to pharmaceutical manufacturing and distribution is contrary to federal health care policy, and the deleterious effects on the public health can hardly be overstated. Moreover, there can be no doubt that, if left to stand, enterprising plaintiffs' attorneys will advance the First Circuit's "stop selling" theory in lawsuits against every other federally regulated manufacturer, contributing to economic balkanization.

ARGUMENT

I. THE PLAIN CONFLICT BETWEEN MUTUAL'S FDCA-IMPOSED FEDERAL LAW DUTIES AND ITS JURY-IMPOSED STATE LAW DUTIES REQUIRES A FINDING OF PREEMPTION.

A. The Claim at Issue Is Preempted Because of the Conflict Between Mutual's Federal and State Law Duties.

The First Circuit erred in rejecting Mutual's preemption defense. Under Section 505(a) of the Federal Food, Drug, and Cosmetic Act (FDCA), formulations of the active ingredient sulindac could not be sold as a drug without preauthorization from the United States Food and Drug Administration (FDA). Pub. L. No. 75-717, § 505(a),

52 Stat. 1040, 1052 (1938) (codified as amended at 21 U.S.C. § 355(a)). With respect to any new drug application (NDA), FDA is required to weigh the safety risks associated with the new drug against the therapeutic benefits it offers, and strike a balance. *See* 21 U.S.C. § 355(d); *see also* 21 C.F.R. § 314.50(d)(5)(viii) (requiring NDAs to include a "summary of the benefits and risks of the drug, including a discussion of why the benefits exceed the risks under the conditions stated in the labeling"). In the case of sulindac, which was originally approved under the trade name Clinoril, one such risk, albeit remote, was the possibility of Stevens-Johnson Syndrome or toxic epidural necrosis (SJS/TEN). That risk has long been known to FDA and is reflected in the required FDA-approved labeling. As acknowledged by the district court, the FDA-approved labeling "expressly listed SJS/TEN as potential adverse reactions." *Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 135, 142 (D.N.H. 2010).

Mutual obtained its approval by satisfying the requirements of Section 505(j) of the FDCA – the provision for expedited approval of generic drugs that are therapeutically equivalent to the innovator (reference drug) product. 21 U.S.C. § 355(j). To gain approval under Section 505(j), Mutual demonstrated that its sulindac: (i) had the same active ingredient as the approved reference listed drug, Clinoril; (ii) was bioequivalent to Clinoril; (iii) was formulated with the same strength, in the same dosage form, and for the same route of administration; and (iv) was labeled identically to Clinoril except for minor variations reflecting a different manufacturer. These "sameness" requirements are intended to ensure that FDA's risk-benefit determination undertaken in the full NDA process applies equally to the proposed generic drug. *See Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 34-

35 (1st Cir. 2012) (acknowledging "statutory 'safe and effective' designation that the original manufacturer had secured and on which Mutual was entitled to piggyback"); 21 U.S.C. § 355(b)(1), (d); *id.* § 355(j)(2)(A); 21 C.F.R. §§ 314.92, 314.94.

As a matter of federal law, Mutual's sulindac could be shipped in interstate commerce only if Mutual continued to maintain the federally required sameness with Clinoril; Mutual could not continue to ship sulindac in commerce if it changed the formulation or labeling of its sulindac drug. As the First Circuit acknowledged, "Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)." *Bartlett*, 678 F.3d at 37. Despite the known risks of sulindac, including the risk of SJS/TEN, FDA determined that the benefit of having sulindac available as a treatment option for prescribers and patients outweighed these risks. Sulindac continues to be sold in interstate commerce, with full FDA approval. *See Bartlett v. Mut. Pharm. Co.*, 760 F. Supp. 2d 220, 228-29 (D.N.H. 2011) ("Sulindac remains on the market to this day, with FDA approval."); *Bartlett*, 678 F.3d at 34 (acknowledging that FDA has "never withdrawn" its "'safe and effective' designation.").

The First Circuit recognized this Court's determination "that the FDCA preempts failure-to-warn claims against generic drug manufacturers [who] . . . unlike brand-name manufacturers cannot unilaterally change their labels, 21 C.F.R. § 314.94(a)(8)(iv), and thus cannot comply with both federal labeling standards and state law requirements deviating from those standards." *Bartlett*, 678 F.3d at 37 (emphasis omitted) (citing *Mensing*, 131 S. Ct. at 2578). The court acknowledged that this Court's rejection of a brand name manufacturer's preemption defense in *Wyeth*

v. Levine, 555 U.S. 555 (2009), a failure-to-warn case on which the First Circuit relied, rested on the possibility "for brand name manufacturers to comply with both federal labeling requirements and state tort law effectively requiring a stronger label." *Bartlett*, 678 F.3d at 37, n.2. That possibility was not available to Mutual as a generic manufacturer.

Nevertheless, clearly distressed by the fact that Bartlett "lost her warning claim by the mere chance of her drug store's selection of a generic," *id.* at 38, the court resorted to sleight of hand to preserve her "design defect" claim. First, the court read *Levine* broadly to reject any "implied preemption" under the FDCA and to endorse state law as a "complementary form of drug regulation." *Id.* at 37. Next, it interpreted *Mensing* as only a limited "exception" *to Levine* and confined *Mensing* to failure-to-warn claims even though *Mensing* turned on the impossibility of PLIVA's complying with its obligations under both federal and state law rather than on any warning-specific principle. *Id.* Emphasizing the general anti-preemption rule it discerned in *Levine*, the First Circuit then distinguished design defect claims from failure-to-warn claims and speculated that "the FDCA might permit states to tell Mutual it ought not be [making the drug at all] if risk-benefit analysis weighs against the drug, despite what the Supreme Court made of similar arguments in the labeling context." *Id.* The court speculated that "the Supreme Court might be less ready to deprive Bartlett of her remaining [design defect] avenue of relief" when its *Mensing* decision had foreclosed her failure to warn claim. *Id.* at 38. Based on that speculation, and the concept that Mutual could comply with New Hampshire's determination that sulindac was unreasonably dangerous by choosing "not to make

the drug at all," even though it was FDA approved, the First Circuit rejected Mutual's impossibility preemption defense. *Id.*

The First Circuit's reasoning rests on a distinction without a difference. The command of federal law to Mutual with respect to the formulation or "design" of its sulindac was identical to the command with respect to the labeling of its sulindac. Mutual could no more change its formulation than it could its labeling while remaining within the bounds of its FDA approval to distribute sulindac in commerce. *See* 21 U.S.C. § 355(j)(2)(A)(ii) (sameness requirement for active ingredient), *id.* § 355(j)(2)(A)(iii) (sameness requirement for route of administration, dosage forms, and strength), *id.* § 355(j)(2)(A)(v) (sameness requirement for labeling). If state law determined Mutual's sulindac to be inadequately labeled or improperly designed, Mutual's only compliant choices under New Hampshire law were to make changes in violation of federal law or withdraw its sulindac from the market. As this Court recognized in *Mensing*, the Supremacy Clause forecloses New Hampshire from imposing that Hobson's choice on Mutual. *See Bartlett*, 678 F.3d at 38 (First Circuit acknowledges that its decision is in "tension" with *Mensing*); *Mensing*, 131 S. Ct. at 2579 ("We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless."); *see also McDermott v. Wisconsin*, 228 U.S. 115, 131-32 (1913) (noting that "the State may not, under the guise of exercising its police powers or otherwise, impose burdens upon or discriminate against interstate commerce, nor may it enact legislation in conflict with the statutes of Congress passed for the regulation of the subject, and if it does, to the extent that the state law interferes with or frustrates the operation of the acts of

Congress, its provisions must yield to the superior Federal power given to Congress by the Constitution.") (finding that state labeling law imposed requirements contrary to federal law and was therefore preempted).

B. Under the Supremacy Clause, FDA's Expert Federal Law Risk-Benefit Analysis Cannot Be Overridden by a Lay Jury Acting Under State Law.

The judgment at issue is premised on a jury finding that sulindac is unreasonably dangerous and "defective" under New Hampshire law; that finding is directly contrary to the expert conclusion of FDA based on its risk-benefit analysis. The injuries suffered by Respondent Bartlett arose from the inherent risk that administration of sulindac could result in SJS/TEN in a small number of patients. *See Bartlett*, 760 F. Supp. 2d at 240. This risk was disclosed in sulindac's labeling and necessarily evaluated by FDA in determining whether the branded reference listed drug, Clinoril, to which Mutual's sulindac was identical, should be approved for national distribution. *See Bartlett*, 731 F. Supp. 2d at 142-43 (discussing labeling of sulindac for SJS/TEN); *Bartlett*, 760 F. Supp. 2d at 229 (rejecting claim that FDA would have revoked approval had it known of risks as "contrary to what actually happened.").

Since the FDCA was amended in 1962, FDA has been required to assess both the risks and benefits of drugs for which approval is sought. S. Rep. No. 87-1744, at 15 (1962); *see also* FDCA § 505(d) (codified as amended at 21 U.S.C. § 355(d)); 21 C.F.R. § 314.50(d)(5)(viii) (requiring new drug applicants to provide a "summary of the benefits and risks of the drug, including a discussion of why the

benefits exceed the risks under the condition stated in the labeling."). FDA necessarily concluded that the Clinoril formulation to which Mutual's sulindac was identical had a positive risk-benefit balance taking into account the known SJS/TEN risk disclosed in its labeling.

As part of its responsibility under the FDCA, FDA collects information about adverse reactions to approved drugs and has the authority to revoke the approval of a drug if its risk-benefit balance becomes unfavorable. 21 U.S.C. § 355(e). FDA has not revoked its approval of Clinoril and thus continues to authorize the interstate distribution of Clinoril and its generic equivalents, including Mutual's sulindac. *See Bartlett*, 760 F. Supp. 2d at 228-29 ("sulindac remains on the market to this day, with FDA approval."); *Bartlett*, 678 F.3d at 34 (FDA has "never withdrawn" its "'safe and effective' designation.").

The New Hampshire jury assessed sulindac's risk-benefit balance using the same factors as FDA but weighed them differently to reach the opposite conclusion. There is no indication in any decision below that the information available to the jury was materially different from the information on which FDA had acted. To the contrary, the plaintiff's evidence at trial was mostly "drawn directly from the medical literature or published FDA analyses." *Bartlett*, 760 F. Supp. 2d at 233-36.[2]

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[2]The Court suggested in *Wyeth v. Levine* that state tort lawsuits may "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." 555 U.S. 555, 579 (2009). But there was nothing new uncovered here; as the lower court opinions reflect, the claim was expressly premised on second-guessing FDA's risk-benefit determination as to a known, labeled risk. *See Bartlett*, 678 F.3d at 38.

As between the competing federal and state risk-benefit balances, the balance struck by FDA under its congressional mandate must prevail, at least absent the kind of evidence arising after FDA's decision that was presented in *Levine*. Article VI of the Constitution unequivocally makes the "Laws of the United States . . . the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the contrary notwithstanding." U.S. Const. art. VI cl. 2. FDA determined that sulindac was legally safe and effective based on essentially the same risk evidence presented to the New Hampshire jury. Any judgment premised on a contrary determination under state law should not stand.

II. THE FIRST CIRCUIT'S "STOP SELLING" THEORY IS ANTITHETICAL TO THE COMMERCE CLAUSE.

A. The Commerce Clause Was Designed To Foster the Free Flow of Commerce in a Single, National Market.

Even apart from well-settled federal impossibility preemption principles, the First Circuit's decision urgently requires reversal because of the threat it poses to the free flow of interstate commerce and the supremacy of federal risk-benefit decisions. The First Circuit's decision endorsed the authority of a state to sanction as wrongful the sale within its borders of a product moving in interstate commerce consistent with its federally mandated composition and labeling. The exercise of that authority by a state contravenes the Commerce Clause and should be rejected by this Court.

The Commerce Clause entrusts Congress with the "Power . . . [t]o regulate Commerce with foreign Nations and among the several States . . .." U.S. Const. art. I, § 8, cl. 3. Promoting the free flow of commerce via a single, national market was a central goal of the 1787 Constitutional Convention and, as anticipated by the Framers, has been a continuing boon to our economy. As James Madison explained, "[t]he defect of power in the existing [Articles of Confederation] to regulate the commerce between its several members [has] been clearly pointed out by experience." THE FEDERALIST, No. 42 (James Madison). Absent federal power to displace conflicting state laws, the Framers feared that "[e]ach State, or separate confederacy, would pursue a system of commercial polity peculiar to itself. This would occasion distinctions, preferences, and exclusions, which would beget discontent." THE FEDERALIST, No. 7 (Alexander Hamilton. As Hamilton elsewhere remarked, "[t]he importance of the Union, in a commercial light, is one of those points about which there is least room to entertain a difference of opinion, and which has in fact commanded the most general assent of men who have any acquaintance with the subject." THE FEDERALIST, No. 11 (Alexander Hamilton). This Court likewise has explained the fundamental importance of the commerce power to the adoption of the Constitution:

> The sole purpose for which Virginia initiated the movement which ultimately produced the Constitution was "to take into consideration the trade of the United States; to examine the relative situations and trade of the said States, and to consider how far a uniform system in their commercial regulations may be necessary

> to their common interest and their permanent harmony."

H.P Hood & Sons, Inc. v. Du Mond, 336 U.S. 525, 533 (1949) (quoting *Formation of the Union*, H.R. Doc. No. 398, 12 H. Docs., 69th Cong., 1st Sess., p. 38).

The union contemplated by the Framers required both that the national government have authority to pass uniform laws governing interstate commerce, and that those laws supersede contrary laws enacted under the authority of the states. As Hamilton stated, "[t]he government of the Union must be empowered to pass all laws, and to make all regulations . . . in respect to commerce." THE FEDERALIST, No. 23 (Alexander Hamilton). That was a principal reason the Framers determined that "[t]he character of such a governme[nt] ought . . . to be paramount to the state constitutions." James Madison, *Notes of the Constitutional Convention* (May 29, 1787), in 1 THE RECORDS OF THE FEDERAL CONVENTION OF 1787, 17-23 (Max Farrand ed., 1911). Thus, the Constitution's combination of the Commerce Clause and the Supremacy Clause created the framework for a national market.

The Commerce Clause both affirmatively empowers Congressional regulatory action and, as this Court has held, bars states from impairing the free flow of interstate commerce. The Court recognized that principle as early as its decision in *Gibbons v. Ogden*, 22 U.S. 1 (1824). There, the Court protected the right of federally licensed steamships to enter the ports and navigate the waters of the State of New York against New York's effort to protect sailing ships by foreclosing steamship activity in its waters and ports. Per Chief Justice Marshall, in words directly

applicable to New Hampshire's determination that Mutual was wrongly selling sulindac under its FDA approval:

> The word "license," means permission, or authority; and a license to do any particular thing, is a permission or authority to do that thing; and if granted by a person having power to grant it, transfers to the grantee the right to do whatever it purports to authorize. It certainly transfers to him all the right which the grantor can transfer, to do what is within the terms of the license.
>
> * * *
>
> ... all inquiry into this subject seems to the Court to be put completely at rest, by the act already mentioned, entitled, "An act for the enrolling and licensing of steam boats."
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> * * *
>
> This act demonstrates the opinion of Congress, that steam boats may be enrolled and licensed, in common with vessels using sails. They are, of course, entitled to the same privileges, and can no more be restrained from navigating waters, and entering ports which are free to such vessels, than if they were wafted on their voyage by the winds, instead of being propelled by the agency of fire. *The one element may be as legitimately used as the other, for every commercial purpose authorized by the laws of the Union; and the act of a State inhibiting*

> *the use of either to any vessel having a license under the act of Congress, comes, we think, in direct collision with that act.*

Id. at 213-14, 220-21 (emphasis added). *Gibbons* thus establishes the primacy of a federal license over any conflicting state restrictions. The importance of the constitutional protection against state impedance of interstate commerce was further articulated by Justice Johnson in his concurring opinion in *Gibbons*: "if there was any one object riding over every other in the adoption of the constitution, it was to keep the commercial intercourse among the States free from all invidious and partial restraints." *Id.* at 231.

This Court has never deviated from the teaching of *Gibbons v. Ogden*. As explained by Justice Cardozo in *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 522-23 (1935), the Court has protected interstate commerce from undue state interference by recognizing that the Constitution was "framed upon the theory that the peoples of the several States must sink or swim together, and that in the long run prosperity and salvation are in union and not division." *See also Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662, 670-71 (1981) (invalidating state restriction on truck length and holding that "the incantation of a purpose to promote the public health or safety does not insulate a state law from Commerce clause attack."). Thus, while states may to some extent apply their police powers to activities in interstate commerce if not preempted by Congress from doing so, they may not exercise those powers to foreclose interstate commerce or effectively exclude their territory from the national market. *See, e.g., Brown-Forman Distillers Corp. v. N.Y. State Liquor*

Auth., 476 U.S. 573, 582-83 (1986) (no State can "project its legislation into [other States]") (citation omitted); *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 525-28 (1959) (invalidating Illinois law that required trucks entering the State to install unique mudflaps).

B. Allowing a State Tort Claim Based on "Second Guessing" a Federal Determination That a Product Could Be Lawfully Manufactured and Sold Would Undermine the National Market Promoted by the Commerce Clause.

The First Circuit interpreted New Hampshire law to permit a jury "second guessing the FDA" to find that Mutual's distribution of sulindac in New Hampshire was wrongful because sulindac failed the jury's risk-benefit balancing. *Bartlett*, 678 F.3d at 37-38. Mutual was then sanctioned by a $21 million award to Bartlett premised on its wrongful conduct. New Hampshire's exercise of the power to enter that award is not meaningfully distinct from the imposition of a ban on sulindac entering New Hampshire enforceable by a civil penalty. This Court has consistently rejected the contention that an award of civil damages is any less an exercise of state regulatory power than a civil penalty payable to the state. *See, e.g., Cipollone v. Liggett Group, Inc.* 505 U.S. 504, 521-22 (1992) (plurality opinion) ("[S]tate regulation can be as effective exerted through an award of damages as through some form of preventive relief." (citation and emphasis omitted)); *see also id.* at 548-49 (Scalia and Thomas, JJ., concurring in relevant part); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) ("[C]ommon-law liability is premised on the existence of a legal duty, and a tort judgment therefore establishes that the defendant has violated a

state obligation. And while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy." (quotation marks and citations omitted)); *Mensing*, 131 S. Ct. 2567 (common law failure-to-warn claim preempted).

Because Mutual's ability to distribute sulindac in New Hampshire was federally conditioned on using the formulation and labeling that New Hampshire found to fail its common law risk-balancing test, the effect of New Hampshire's decision was to foreclose any non-tortious distribution of Mutual's sulindac in New Hampshire. As the First Circuit acknowledged, Mutual's only lawful course of action to satisfy both federal and state requirements was to "choose not to make the drug at all," *Bartlett*, 678 F.3d at 37, a result in conflict with the Commerce Clause and requiring reversal by this Court. Like the federal license upheld in *Gibbons v. Ogden*, FDA's nationwide authorization to sell, granted only after an extensive approval process, would have far less value if it could be superseded by contrary jury determinations in any or all states. This is not the national market contemplated by the Framers.

The First Circuit's decision advises Mutual that it may comply with both federal and state law by not making and selling sulindac for use in New Hampshire. *Bartlett*, 678 F.3d at 37. The consequences of the New Hampshire judgment, however, cannot be easily confined to New Hampshire. When a product like sulindac is distributed nationally through multiple distribution entities and layers – *e.g.*, wholesalers' warehouses, pharmacy chains, etc. – restricting its availability in a single state is a complex

problem. As a practical matter, keeping sulindac out of New Hampshire could require ceasing to distribute it at all or at least restricting its distribution in adjacent states that New Hampshire residents can readily access. Moreover, sulindac cannot be labeled to exclude use in New Hampshire, even assuming that such labeling would be effective, because Mutual is not permitted to change its FDA-approved label. 21 U.S.C. § 355(j)(2)(A)(v); *Bartlett*, 678 F.3d at 37 ("generic makers cannot alter the labeling."). Nor is it apparent how a manufacturer could be expected to know that in New Hampshire, but only in New Hampshire, its FDA-approved drug could be deemed "defective." *Cf. Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001) ("As a practical matter, complying with FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants – burdens not contemplated by Congress in enacting the FDCA and the MDA.").

The spillover of New Hampshire's law into other states raises the type of Commerce Clause problems this Court has addressed by foreclosing enforcement of state laws with troublesome extraterritorial effects. In our federal union, states must limit their regulatory initiatives to their own territory; this Court has not hesitated to strike down state laws that effectively constrain activities otherwise permissible in sister states. *Healy v. Beer Institute*, 491 U.S. 324, 335-36 (1989) (observing that the Constitution has a "special concern both with the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce and with the autonomy of the individual States within their respective spheres" (footnote omitted)) (invalidating

state price-posting statute based on extraterritorial effects). As this Court most recently stated in *BMW v. Gore*, 517 U.S. 559, 570-72 (1996): "one State's power to impose burdens on the interstate market . . . is not only subordinate to the federal power over interstate commerce, but is also constrained by the need to respect the interest of other States." Manufacturers distributing in interstate commerce and consumers in states other than New Hampshire that seek to benefit from sulindac (as well as New Hampshire consumers) should not be foreclosed from accessing sulindac by a New Hampshire jury's idiosyncratic disagreement with FDA's balancing of sulindac's risks and benefits.

III. THE FIRST CIRCUIT'S "MARKET WITHDRAWAL" THEORY EVISCERATES THE PREEMPTION DEFENSE AND THREATENS ECONOMIC BALKANIZATION.

If accepted by this Court, the consequences of the First Circuit's market withdrawal approach could hardly be overstated. The impacts will, of course, be most immediately and obviously felt in the nation's health care system. Instead of one national, expert agency reviewing and approving drugs, there could be fifty state regulatory agencies plus unlimited individual jury outcomes making inconsistent determinations as to the proper design and availability of drugs. Even if the national drug distribution system could somehow be redesigned to take into account state-by-state variations in the lawfulness (and, thus, availability) of certain drugs, the impact on the distribution of drugs and the practice of medicine would be immense. The treatment of patients would vary more from state to state, as some FDA-approved drugs would

be unavailable to physicians in some states (*e.g.*, per the First Circuit's suggestion, sulindac in New Hampshire). The teaching and practice of medicine would become increasingly balkanized, to the detriment of physicians, patients, and the federal government itself, which by statute is deeply integrated into the health care system. *See, e.g.*, Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965) (establishing Medicare and Medicaid); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 111 (2010). Not only would the quality of care decrease, the cost of drugs inevitably would increase as distribution became less efficient.

In addition to the problems inherent in having multiple decision-makers concerning the availability of individual drugs, FDA's risk-benefit analyses should be favored because they are objectively better in promoting public health than equivalent determinations by votes of lay jurors. In determining whether to approve an NDA, FDA relies on its experienced staff and panels of trained medical and pharmacological experts; there is no suggestion that the lay jury in New Hampshire had the benefit of such expertise. *See, e.g., Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653-54 (1973) ("[t]he determination whether a drug is generally recognized as safe and effective . . . necessarily implicates complex chemical and pharmacological considerations."). FDA review of an NDA typically includes a year or more of close analysis; a jury trial may take a few days or weeks. FDA must balance the benefits of the proposed drug to the entire treatable population against the potential incidence of its known risks. In contrast, however instructed, a jury's attention cannot help but be focused on a single, grievously injured individual, particularly with skilled

plaintiffs' counsel maintaining that focus. *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. at 325 ("A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."). This focus magnifies the drug's risks and effectively nullifies its benefits. As Congress has established, and for the benefit of the health care system as a whole, the safety and efficacy of drugs is properly determined by FDA, based on controlled studies and judgments made by trained physicians and other scientists, not lay jurors in a courtroom determining whether a sympathetic plaintiff should be compensated for her injuries by a large drug company.

There is also ample reason to expect that the First Circuit's "stop selling" approach would spread beyond the pharmaceutical industry. If allowed to stand, the First Circuit's rationale will undoubtedly be relied upon in lawsuits involving the many federally regulated products that, like drugs, inherently carry some degree of risk, no matter how well they are designed. The availability of those products confers a benefit on society and to the economy as a whole. Where expert federal agencies make risk-benefit determinations that allow the marketing of such products, those assessments should not be overridden by state tort systems, especially in the absence of evidence of risks not considered by the agency.

A system such as that contemplated by the First Circuit, in which individual juries would retroactively second guess expert federal risk-benefit determinations based on application of malleable state tort standards, would allow sympathy for the few unpredictably but inevitably injured by these inherent risks to override the

interests of the many who would benefit from continued distribution. As the First Circuit itself hinted, *see* 678 F.3d at 44, confusing tort concepts of wrongful conduct and welfare interests of aiding the injured is bad public policy. If left intact, the First Circuit's decision will no doubt be used as a "stop selling" loophole to the federal preemption defense to products liability lawsuits – a defense that that enhances overall public welfare by serving as a bulwark against economic balkanization, helping to ensure that products whose risks outweigh their benefits remain in lawful distribution.

CONCLUSION

For the foregoing reasons, the judgment under review should be reversed.

January 22, 2013

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AMICUS CURIAE BRIEF

RECORD
AND
BRIEFS

No. 12-142

IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF THE COUNCIL OF STATE GOVERNMENTS AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICI CURIAE*[1]

Amicus curiae, the Council of State Governments ("CSG"), is the Nation's only organization serving all three branches of state government. CSG is a region-based forum that fosters the exchange of insights and ideas to help state officials shape public policy. This offers unparalleled regional, national and international opportunities to network, develop leaders, collaborate, and create problem-solving partnerships.

All three branches of state government play roles in the development and evolution of traditional state tort law doctrines and liability rules. State legislatures and governors may enact legislation that alters or abrogates traditional common law tort liability rules, including products liability law. Further, state courts traditionally have played a leading role in the development and application of state tort law. For these reasons, all branches of state governments in general have an interest in retaining state sovereignty and control over the substance of state tort law, without expansion of implied federal pre-emption doctrines that may frustrate and defeat state law.

SUMMARY OF ARGUMENT

The question for this Court is whether federal law impliedly pre-empts longstanding, traditional tort liability for selling unreasonably dangerous products in the context of prescription drugs produced by generic manufacturers. The answer is no.

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[1] Counsel for *amicus curiae* authored this brief in its entirety. None of the parties or their counsel, nor any other person or entity other than *amicus* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Consent letters from counsel for both petitioner and respondent for the filing of *amicus curiae* briefs are on file with the Clerk. Sup. Ct. R. 37.6.

The Court adopted the correct approach to prescription drug pre-emption in large part in *Wyeth v. Levine*, 555 U.S. 555 (2009), when it held that state law inadequate warning claims against brand name manufacturers of prescription drugs were not pre-empted because state law did not "conflict[] with the text of the relevant federal statute or with the federal regulations authorized by that text." 555 U.S. at 588 (Thomas, J., concurring). In other words, "the relevant federal law did not give Wyeth a right that the state-law judgment took away." *Id.* at 593. Based on clear provisions of the same federal statutes, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), held that a state law failure to warn claim against generic prescription drug manufacturers is pre-empted.

Both cases, however, involved a narrow and specific state law claim premised on a manufacturer's duty to provide adequate warnings, a claim that is fundamentally different than the more general design defect claim at issue in this case. Furthermore, the argument that the FDA has taken over the regulation of the *content of warnings* for prescription drugs is far stronger than any argument that the FDA has monopolized the business of providing compensation for patients injured by unreasonably dangerous prescription drugs. *Cf. Cipollone v. Liggett Group*, 505 U.S. 504 (1992) (recognizing significant federal role regarding warnings in the context of tobacco regulation). The latter notion simply is not borne out by the relevant federal statutes and regulations.

The Court in the prescription drug pre-emption cases has focused on impossibility analysis, not the theory of so-called "obstacle" pre-emption, and with good reason – there is no evidence of congressional intent to pre-empt traditional state tort law in this

arena. Moreover, a majority of the Court continues to apply a presumption against pre-emption in implied "conflict" cases such as this one. Petitioner and its *amici* effectively invite the Court to disregard both of these fundamental propositions, in particular by asking the Court to engage in a free-wheeling "obstacle" inquiry and effectively to apply a "presumption *in favor of* pre-emption."

The Court, instead, should reject those invitations and apply "impossibility" pre-emption and the traditional presumption against pre-emption. Only "[w]here state and federal law 'directly conflict'" must state law "give way," *Mensing*, 131 S. Ct. at 2577 (quoting *Wyeth*, 555 U.S. at 583 (Thomas, J., concurring)), and there is no such direct conflict here, because federal law does not require Petitioner to sell Sulindac. The mere fact that the Hatch-Waxman Amendments in part promote the use of generic drugs does not equate to an intention to promote generics "at all costs." *Cf. Williamson v. Mazda Motor of America*, 131 S. Ct. 1131, 1139 (2011); DAN DOBBS, THE LAW OF TORTS at 1036 (2000). Moreover, the Court recognizes that Congress legislates against the backdrop of traditional common law norms such as the design defect doctrines at issue here.

Ultimately, the "general rule" of no pre-emption that the Court recognized in *Wyeth* counsels strongly against extending the limited pre-emption holding of *Mensing* to the distinct and more fundamental category of state law tort liability for design defects. The tort law standards to prove a design defect claim may be high, but that decision is for the States to make; the federal courts should not grant manufacturers a legal immunity in the guise of implied pre-emption

when Congress has not mandated – or even suggested – that result.

Finally, if New Hampshire has, as Petitioner and its *amici* suggest, truly crafted a body of tort law unique to the Granite State, and FDA may soon eliminate pre-emption of inadequate warning claims against generic manufacturers (as the United States now suggests, U.S. Br. 15 n. 2), then the Court should not expend its resources to decide a case that does not involve the question whether design defect claims in general are pre-empted by federal law in cases involving prescription drugs. Instead, it may be appropriate for the Court to consider dismissing the case as improvidently granted or to certify disputed issues of New Hampshire tort law to the New Hampshire Supreme Court.

ARGUMENT

I. IN THE PRESCRIPTION DRUG CONTEXT, THE COURT FOCUSES ON THE "IMPOSSIBILITY" PRE-EMPTION ANALYSIS — NOT "OBSTACLE" PRE-EMPTION.

The Court should only apply traditional "impossibility" pre-emption to resolve this case. Petitioner and its *amici*, however, invite this Court to do considerable violence to the Court's general pre-emption principles, including no less than asking the Court (1) to engage in a free-wheeling judicial inquiry under the guise of "obstacle" pre-emption, and (2) to adopt a presumption in favor of pre-emption in the context of prescription drugs. Ultimately, the question the Court must resolve here is whether it wants to be drawn into "policing" imaginary lines, lines that Congress did not draw—indeed lines that Congress has declined to draw—and which fail to accord any

respect to state tort law, all in furtherance of a tort reform agenda thinly disguised as a constitutional pre-emption analysis. With all due respect, the Court's answer should be an emphatic "no thanks."

From an analytical standpoint, this case is on a par with *Wyeth v. Levine*, 555 U.S. 555 (2009), and *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011), in the sense that the Court's primary focus in all of the prescription drug cases has been on so-called "impossibility" pre-emption. The Court long has recognized that state and federal law are most obviously in conflict—and state law therefore necessarily pre-empted—when "compliance with both federal and state regulations is a physical impossibility." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). As *Wyeth* and *Mensing* reiterated, impossibility pre-emption doctrine remains the focus in prescription drug cases.

A. Petitioner and its *amici*, however, invoke so-called "obstacle" pre-emption, which may operate where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Simply put, this doctrine has no role here.

To begin, there are strong constitutional arguments against the invocation of "obstacle" pre-emption in any case, because obstacle pre-emption allows federal courts "to vacate a judgment issued by another sovereign based on nothing more than assumptions and goals that were untethered from constitutionally enacted federal law." *Williamson v. Mazda Motor of America, Inc.*, 131 S. Ct. 1131, 1141-43 (2011) (Thomas, J., concurring); *Wyeth*, 555 U.S. at 604 (Thomas, J., concurring) (the doctrine "leads to decisions giving improperly broad pre-emptive ef-

fect to judicially manufactured policies"); *Pharm. Research & Mfrs of Am. v. Walsh*, 538 U.S. 644, 678 (2003) (Thomas, J., concurring in judgment); *Camps Newfound / Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 617 (1997) (Thomas, J., dissenting).[2] For these reasons, one Justice has rejected the entire concept of "obstacle" pre-emption, *id.*, while four others have expressly acknowledged that such an analysis threatens to result in a "free-wheeling judicial inquiry into whether a state [law] is in tension with federal objectives," *Chamber of Commerce v. Whiting*, 131 S. Ct. 1968, 1985 (2011), and to "undercut the principle that it is the Congress rather than the courts that pre-empts state law." *Id.* (quoting *Gade*

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[2] In addition, obstacle pre-emption "encourages an overly expansive reading of statutory text" and "inevitably leads [courts] to assume that Congress wanted to pursue those policies 'at all costs' – even when the text reflects a different balance." *Wyeth*, 555 U.S. at 601 (Thomas, J., concurring). Indeed, there is no factual basis for the Court to assume "that every policy seemingly consistent with federal statutory text has necessarily been authorized by Congress and warrants pre-emptive effect." *Id.* at 602. *Cf.* Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 280 (2000) (even if the Court were to "suppose that all members of Congress can agree on the 'full purposes and objectives' behind a particular federal statute[,] [t]here still is no reason to assume that they would want to displace whatever state law makes achieving those purposes more difficult."); *id.* at 281 (the "mere fact that Congress enacts a statute to serve certain purposes ... does not automatically imply that Congress wants to displace all state law that gets in the way of those purposes.") *See, e.g.*, *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm.*, 461 U.S. 190, 222 (1983) (a federal law encouraging the use of nuclear power did not pre-empt the States' authority to decline to issue a license to build a nuclear plant because Congress' purpose of "the promotion of nuclear power is not to be accomplished 'at all costs'").

v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring)).

Indeed, obstacle preemption finds its best—and likely only legitimate—home in federal common law cases. In that rare—and notably statute-free—zone, "obstacle" pre-emption may properly apply because the "conflict with federal policy need not be as sharp as that which must exist for ordinary pre-emption when Congress legislates." *Boyle v. United Technologies Corp.*, 487 U.S. 500, 507 (1988). This federal common law fit serves to highlight that the Court acts as a quasi-legislature when it applies "obstacle" preemption doctrine. *Cf. O'Melveny & Myers v. FDIC*, 512 U.S. 79, 89 (1994) (holding that the weighing of factors, beyond statutory text and structure, in the proposed creation of federal common law is more appropriately a legislative function). While that legislative role may be appropriate in limited circumstances such as the federal common law of foreign relations, see *Zschernig v. Miller*, 389 U.S. 429, 441 (1968) (applying obstacle pre-emption to further judicially presumed federal foreign policy goals because Congress had not spoken to the issue), exercising such power is inappropriate here where the Court sits in its traditional role of interpreting statutes. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 388–91 (2000) (Scalia, J., joined by Thomas, J., concurring) (when presented with a statute, pre-emption analysis must focus solely on the text).

Finally, several Justices have sworn off quasi-legislative dalliances akin to those embedded in "obstacle" pre-emption doctrine in the closely related field of implied causes of action. *See Alexander v. Sandoval*, 532 U.S. 275, 287 (2001) ("Having sworn off the habit of venturing beyond Congress's intent,

we will not accept respondents' invitation to have one last drink."); *Correctional Services Corp. v. Malesko*, 534 U.S. 61, 75 (2001) (Scalia, J., joined by Thomas, J., concurring) (implied cause of action doctrine "is a relic of the heady days in which this Court assumed common-law powers to create causes of action."). Thus, the barkeep has already yelled "last call" on legislating from the bench in the guise of enforcing amorphous federal goals, and the Court should reject Petitioners' invitation for one more round.[3]

B. In any event, in *Wyeth*, the Court effectively rejected the claim that obstacle pre-emption operates in prescription drug cases, and the Court's most recent decision relied solely and exclusively on an impossibility pre-emption analysis. *Mensing*, 131 S. Ct. at 2577 n. 4 ("We do not address whether state and federal law 'directly conflict' in circumstances beyond 'impossibility'"). The Court should similarly limit its consideration in this case.

The intent of Congress "'is the ultimate touchstone in every pre-emption case.'" *Wyeth*, 555 U.S. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). In *Wyeth*, the Court emphasized that Congress is well aware of the existence of state tort litigation involving FDA-approved drugs, and yet Congress has never purported to pre-empt any state law tort claims involving prescription drugs. That state of

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[3] Moreover, the Court of Appeals in this case did not address obstacle pre-emption, and Petitioner's Question Presented in its petition for a writ of certiorari identified the decision below as in conflict with *Mensing*, but *Mensing* is undeniably and solely based on impossibility pre-emption. 131 S. Ct. at 2577 n. 4. Thus, the Court could reject Petitioner's belated efforts to make this an obstacle pre-emption case on procedural as well as substantive grounds.

affairs contrasts sharply with Congress' enactment of an express pre-emption provision regarding medical devices. *See Wyeth*, 555 U.S. at 574 (Congress did not "enact[] such a provision for prescription drugs").

Nor does the fact that this case involves generic prescription drug manufacturers change the analysis or holding of *Wyeth* rejecting "obstacle" pre-emption, because "[t]he Hatch-Waxman amendments [addressing generic drugs] contain no provision expressly pre-empting state tort claims." *Mensing*, 131 S. Ct. at 2577 n. 5. Instead, the congressionally drawn distinction between prescription drugs (brand name or generic) on the one hand, and medical devices on the other, "is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Wyeth*, 555 U.S. at 575 (citing *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989) ("The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them.") (internal quotation marks omitted)). *See also Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984) (the Price-Anderson Act does not pre-empt state tort actions arising from accidents at nuclear facilities because "in enacting and amending the Price-Anderson Act, Congress assumed that state law remedies ... were available to those injured by nuclear incidents" even though "there is tension between the conclusion that safety regulation is the exclusive concern of the federal law and the conclusion that a State may nevertheless award damages based on its own law of liability.")

II. THE COURT APPLIES A "PRESUMPTION AGAINST PRE-EMPTION" IN IMPLIED PRE-EMPTION CASES.

A. Petitioner's arguments, and those of its *amici*, seem to start with a presumption *in favor of* pre-emption, which is of course exactly backwards. One of the cornerstones of pre-emption doctrine is that courts presume that Congress does not intend to displace state law, particularly in areas of traditional state concern and where the States traditionally have exercised their police powers: "Consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *see also Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008) ("When addressing questions of express or implied pre-emption, we begin our analysis 'with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'") (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

The presumption *against* pre-emption arises from the Court's recognition of the fundamental nature of federalism and dual sovereignty under the Constitution. Indeed, the presumption acts to "further the spirit of *Garcia* [*v. San Antonio Metropolitan Transit Auth.*, 469 U.S. 528 (1985)] by requiring that decisions restricting state sovereignty be made in a deliberate manner by Congress, through the explicit exercise of its lawmaking power ...." LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW § 6-28, at 1175-76 (3d ed. 2000). *Cf. Gregory v. Ashcroft*, 501 U.S. 452, 464 (1991).

Although the argument for applying a presumption against pre-emption may be strongest in the context of claims of express pre-emption, the principle also has force in the implied pre-emption context, as the Court has recognized. Indeed, in *Wyeth*, the Court reaffirmed the applicability of the presumption in precisely this context:

> Wyeth argues that the presumption against pre-emption should not apply to this case because the Federal Government has regulated drug labeling for more than a century. That argument misunderstands the principle: We rely on the presumption because respect for the States as "independent sovereigns in our federal system" leads us to assume that "Congress does not cavalierly pre-empt state-law causes of action." The presumption thus accounts for the historic presence of state law but does not rely on the absence of federal regulation.
>
> For its part, the dissent argues that the presumption against pre-emption should not apply to claims of implied conflict pre-emption at all, but this Court has long held to the contrary.

Wyeth, 555 U.S. at 565 n. 3.

Recently, four members of the Court reiterated that the danger of a "free-wheeling judicial inquiry into whether a state [law] is in tension with federal objectives," is that it will "undercut the principle that it is the Congress rather than the courts that preempts state law." *Whiting*, 131 S. Ct. at 1985 (2011) (quoting *Gade*, 505 U.S. at 111 (Kennedy, J., concurring)). Thus, the same four Justices endorsed the proposition that "[o]ur precedents 'establish that *a high threshold must be met* if a state law is to be pre-empted for conflicting with the purposes of [a]

federal Act.'" *Id.* (emphasis added) (quoting, *Gade*, 505 U.S. at 110 (Kennedy, J., concurring)).

More to the point, five Justices rejected Petitioner's "no presumption against pre-emption" position in *Mensing*. To be sure, a plurality of the Court discussed the notion that the Supremacy Clause "suggests that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law." *Mensing*, 131 S. Ct. at 2579–80 (plurality opinion). But just as assuredly, Justice Kennedy declined to join that section (III.B.2.) in *Mensing*, *id.* at 2572 n.*, and the four dissenting Justices embraced the traditional presumption against pre-emption. *Id.* at 2589 (Sotomayor, J., dissenting). Because nothing distinguishes this case from *Mensing* or *Whiting* vis-à-vis the presumption against pre-emption, a majority of the Court favors continued application of the venerable rule here.

B. In fact, applying the presumption in "impossibility" conflict cases makes perfect sense for several reasons. **First**, state law often provides the only remedy for injured persons, and courts should be particularly reluctant to extinguish the only avenue of relief for potentially catastrophic harm. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002); *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449-50 (2005). **Second**, federal statutes and regulations often reflect compromises between those advocating stricter federal standards and those seeking more lenient standards in exchange for not displacing additional state law standards. *Wyeth*, 555 U.S. at 601 (Thomas, J., concurring) ("Federal legislation is often the result of compromise between legislators" and thus "a statute's text might reflect a compromise between parties who wanted to pursue a particular goal to different

extents"). **Third**, Congress might well want additional enforcers on patrol, watching for dangerous drugs, especially given the limited resources and massive responsibilities of federal agencies such as FDA. *Wyeth*, 555 U.S. at 578 (noting FDA's "limited resources to monitor the 11,000 drugs on the market"). **Fourth**, state-law litigation or regulatory action often produce new information about product safety, information that may be of great value and assistance to federal regulators. *Id.*, at 579.

These considerations—the multiple rationales for the presumption against pre-emption—apply with force no matter the nature of the claim of pre-emption. If Congress wants a federal regulatory regime to operate exclusive of state regulation, Congress has the power to achieve that goal. But Congress must make its intent clear in order to overcome the presumption; otherwise a court finding pre-emption will be undermining the political accountability of Congress, shielding Congress from potentially unpopular political reaction to overreaching federal schemes.

Thus, before a court concludes that is it impossible for an actor to comply with both federal and state law requirements, the court should give the benefit of the doubt to according state law a place, particularly when state law traditionally has had a significant role in the area at issue. If there is any ambiguity about whether compliance with the laws of both sovereigns is impossible, the presumption favors a conclusion that there is no pre-emption. If Congress disagrees with a court giving state law that benefit of the doubt, Congress can amend the relevant statute(s) to take away the presumption in particular areas. *See Circuit City Stores, Inc. v. Adams*, 532 U.S.

105, 120 (2001) ("It is for the Congress, not the courts, to consult political forces and then decide how best to resolve conflicts in the course of writing the objective embodiments of law we know as statutes.") (Kennedy, J.).

III. THE HATCH-WAXMAN AMENDMENTS DO NOT PRE-EMPT THE TRUE DESIGN DEFECT CLAIMS AT ISSUE HERE.

Turning to this case, the bottom line is inescapable: The Hatch-Waxman Amendments do not pre-empt design defect claims against the manufacturers of generic prescription drugs.

Unlike the narrower inadequate warning claim which effectively assumes that the plaintiff would have no claim if additional or different warnings been given, a design defect claim in some states may starkly present the all-or-nothing choice for a defendant to, as Petitioner puts it, "stop selling" the offending and harmful product if it wants to avoid the prospect of liability. That notion is neither new nor unusual in the context of common law tort principles. Could the producers (brand name or generic) of the anti-miscarriage drug commonly known as DES, *see, e.g.*, *Sindell v. Abbott Laboratories*, 26 Cal.3d 588, 607 P.2d 924 (1980), have avoided all liability simply by including more detailed warnings on their product? The answer is no, because there is a well-established tort law distinction between a design defect claim and an inadequate warning claim.

"Impossibility pre-emption is a demanding defense." *Wyeth*, 555 U.S. at 573. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Mensing*, 131 S. Ct. at 2579; *see also*

Wyeth, 555 U.S. at 588 (Thomas, J., concurring) ("Pre-emption must turn on whether state law conflicts with the text of the relevant federal statute or with the federal regulations authorized by the text"); *Mensing*, at 2582 (Sotomayor, J., dissenting) ("We have traditionally held defendants claiming impossibility to a demanding standard"), 2587 ("a defendant seeking to set aside state law bears the burden to prove impossibility"). Nothing in the jury's finding on the record in this case that the risks of Petitioner's drug outweigh its benefits requires Petitioner to violate federal law. Nor does Petitioner need "the Federal Government's special permission and assistance," *id.* at 2581, in order to comply with state law.

In *Mensing*, by contrast, if the warnings were inadequate, the defendant there could not change or add to the warnings without violating federal law. In the context of a claim based on the sale of a product that is unreasonably dangerous because its risks outweigh its benefits, the drug company may not be able to change the design or composition of the drug, but the feasibility of an "alternative design" is not the only measure of liability under traditional state law on design defects. Rather, as the Restatement recognizes, even drugs that cannot be designed in any different, safer way, may still result in liability for the manufacture if the drug remains unreasonably dangerous or defective in light of the relevant circumstances, as explained in Part IV below. Only "[w]here state and federal law 'directly conflict'" must state law "give way." *Mensing*, 131 S. Ct. at 2577 (quoting *Wyeth*, 555 U.S. at 583 (Thomas, J., concurring)).

Furthermore, the touchstone of pre-emption is the intent of Congress, but there is no evidence of congressional intent to pre-empt design defect claims:

"The Hatch-Waxman Amendments contain no provision expressly pre-empting state tort claims." *Mensing*, 131 S. Ct. at 2577 n. 5. Further, as the Court recognized in *Williamson*, 131 S. Ct. at 1139, it is wrong to "treat all [] federal standards as if they were maximum standards, eliminating the possibility that the federal agency seeks only to set forth a minimum standard potentially supplemented through state tort law." *Id.* In fact, "[f]ood and drugs are regulated heavily, but with no obvious preemptive intent." DAN DOBBS, THE LAW OF TORTS at 1036 (2000).

Here, Respondent is not asking the Court to "distort federal law to accommodate conflicting state law," *Mensing*, 131 S. Ct. at 2580, because there is no conflicting state law. "Indeed, in protecting our constitutional government, 'the preservation of the States, and the maintenance of their governments, are as much within the design and care of the Constitution as the preservation of the Union and the maintenance of the National government." *Wyeth*, 555 U.S. at 585 (Thomas, J., concurring) (quoting *Texas v. White*, 74 U.S. (7 Wall.) 700, 725 (1869)).

Despite Petitioner's protestations against a "stop-selling" rule, as respondent explains, New Hampshire's law of strict products liability requires only that petitioner compensate respondent for her injuries. *See* Resp. Br. 18-23. Moreover, the notion that state law might impose liability on one who sells an unreasonably dangerous product is far from radical. Traditional state tort law takes the position that, in some instances, the proper option for a product manufacturer that does not want to incur liability for selling an unreasonably dangerous product is to stop selling the product, not just to include or expand a

warning label, or to try redesigning the product. According to the Third Restatement, "[s]ome courts, for example, while recognizing that in most cases involving defective design the plaintiff must prove the availability of a reasonable alternative design, also observe that such proof is not necessary in every case involving design defects." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2, comment b (1997).

Thus, some states, including New Hampshire, hold that manufacturers of unreasonably dangerous products may have to choose between paying damages for the harm caused or removing the product from the market, *i.e.*, not to sell it at all, because there may not be any alternative design that makes the product reasonably safe. *See, e.g.*, *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1183 (N.H. 2001) ("while proof of an alternative design is relevant in a design defect case, it should be neither a controlling factor nor an essential element that must be proved in every case"), *id.* at 1184 ("the rigid prerequisite of a reasonable alternative design places too much emphasis on one of many possible factors that could potentially affect the risk-utility analysis"); *O'Brien v. Muskin Corp.*, 463 A.2d 298, 306 (N.J. 1983) ("even if there are no alternative methods of making bottoms for above-ground pools, the jury might have found that the risk posed by the pool outweighed the utility."); *Potter v. Chicago Pneumatic Tool Co.*, 694 A.2d 1319, 1327-1336 (Conn. 1997) (alternative design is only one factor to be considered, not a requirement for liability); *McCarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1997) (applying New York law and concluding that "the risk of injury to be balanced with the utility is a risk not intended as the primary function of the product. There is no reason to search for

an alternative safer design where the product's sole utility is to kill and maim").

Traditional state tort law, then, may find that some products, given their inherent qualities, are so dangerous that the risks of harm to users substantially outweigh any benefits to the public. That notion is not novel in state tort law. Nor has Congress even remotely expressed intent to pre-empt state laws that give effect to that tradition. *Cf. Bruesewitz v. Wyeth*, 131 S. Ct. 1068, 1080 (2011) (noting the Court's previously expressed "doubt that Congress would quietly pre-empt product-liability claims without providing a federal substitute"); *United States v. Locke*, 529 U.S. 89, 108 (2000) (courts should be particularly reluctant to find implied pre-emption with regard to "medical negligence," a state liability area much like products liability, because it is "a subject historically regulated by the States"). This Court should not use the theory of impossibility pre-emption to do what Congress has declined to do.

Ultimately, nothing in federal law requires Petitioner to sell any particular generic drug, so it is not impossible for Petitioner to comply with both federal and state law here, even assuming that state law indicates that selling the drug at all is unwarranted under tort principles. To stop sales of the drug will not violate federal law, but to keep selling it may well violate state law, and certainly may result in serious harm to some users of the drug. In other words, in a design defect case, state law does not impose any affirmative duty on a drug manufacturer that federal law prohibits the manufacturer from fulfilling. That simple fact distinguishes this case from *Mensing*, and supports application of the general rule of *Wyeth* that state law tort claims are not pre-empted here.

IV. PETITIONER CONFLATES DESIGN DEFECT AND INADEQUATE WARNING CLAIMS, CONTRARY TO FUNDAMENTAL TORT LAW PRINCIPLES.

Petitioner and its *amici* seem to recognize that *Mensing* does not apply to a true design defect claim, so they float the ruse that design defect and inadequate warning doctrines are really the same. In so doing, they rely heavily on *Kurns v. Railroad Friction Prod. Corp.*, 132 S. Ct. 1261 (2012), for the erroneous proposition that such claims are interchangeable in determining whether FDA regulation pre-empts state law tort claims. Their argument is fundamentally wrong, both as a matter of substantive tort law and because *Kurns* involved field pre-emption, not impossibility pre-emption.

A. Tort Law Distinguishes Between Manufacturing, Design and Warning Defect Claims.

Traditional tort law originally based liability for harm caused by products on theories of negligence and implied warranty. DOBBS, at §§ 352-353; DAN DOBBS, ET AL., PROSSER AND KEETON ON TORTS §§ 95A-96 (5th ed. 1984). But since at least the 1960s, the common law and the Second Restatement of Torts have recognized three distinct theories for products liability in addition to traditional negligence claims: (1) manufacturing defects, (2) design defects, and (3) inadequate warnings. DOBBS, at 975 and n. 12; PROSSER, at § 97. In this case, it is important to recognize the distinction between design defect and inadequate warning claims.

Unlike both *Wyeth* and *Mensing*, both of which involved much narrower inadequate warning claims,

this case involves the issue whether federal law pre-empts the more general *design defect* claims. As the Court of Appeals here posited, the distinction between these claims is clear and of legal significance in a case involving a claim of implied *impossibility* pre-emption, not *field* pre-emption.

Field pre-emption – the claim at issue in *Kurns* – necessarily is concerned with *any* tort claim that touches upon the general area of law in which Congress has allegedly pre-empted state regulation. Impossibility pre-emption, in stark contrast, depends critically on the precise nature of the underlying state tort duty; only by comparing the state-law duty under each basis for potential liability and the options available to comply with both federal and state law can a court determine whether simultaneous compliance is "impossible."

Petitioner and its *amici* appear to proceed from the premise that all tort law claims for liability caused by prescription drugs are the same, or at least interchangeable, for pre-emption purposes. Such an assertion fundamentally misstates general tort law products liability principles, and if accepted likely would lead a court to engage in a blunderbuss field pre-emption analysis rather than the carefully nuanced impossibility analysis this Court in fact has applied to such claims. A broad legal immunity from state tort liability may well be the goal of Petitioner and its *amici*, but that goal would be more appropriately sought in Congress if at all, not in this Court in the guise of implied pre-emption analysis.

1. *The Restatement (Second) of Torts Section 402A Recognized Three Distinct Theories.*

Originally, products liability claims were evaluated as negligence or implied warranty claims, with im-

portant limiting doctrines (like "privity" between the seller and the person harmed) that restricted liability. DOBBS, at §§ 352-53. But around 1960, some state courts began applying a broader notion of liability for harm caused by products, what some termed "strict" liability. *Id.* at § 353. That shift in conceptualization gained considerable momentum when "Dean Prosser, drafting the Restatement Second of Torts, picked up [that] idea and incorporated it in a new section, § 402A." *Id.* at 974.

"Section 402A provided that if a product was defective and the defect caused harm, liability would be imposed upon the manufacturer and distributors, *whether or not they were at fault* and whether or not they were in privity with the plaintiff." DOBBS, at 974-75 (emphasis added). Section 402A proved to be very influential in the state courts, which "widely adopted § 402A and regarded it as their guide, philosopher, and friend." *Id.* at 975. Importantly for the pre-emption issue in this case, "[a]fter the promulgation of § 402A, courts and writers began to think that three types of product defect should be distinguished from one another. These were (1) manufacturing defects or production flaws, (2) design defects, and (3) information or warning defects, also called 'marketing defects.'" *Id.* "These categories are now generally recognized." *Id.* at n. 12. *Cf.*, PROSSER at 695 (identifying the same three categories).

When evaluating a design defect claim under the Second Restatement, courts "generally adopted a risk-utility test to determine whether a harmful design is also a defective design." DOBBS, at 980-81. The more recent Products Liability Restatement (discussed in the next subsection) "adopts the risk-utility test of defectiveness." *Id.* at 981, 985.

It is true that the Restatement Second's Comment k provided an exception to the rule of strict liability "for unavoidably dangerous products if a proper warning was given." DOBBS, at 989. But the Second Restatement did not thereby convert all design defect claims into inadequate warning claims as Petitioner and its *amici* effectively claim. Rather, the two claims remained largely distinct and separate, with inadequate warning claims well-recognized as a much narrower category than design defects. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1, Comment a, n.1.

2. *The Products Liability Restatement Expressly Recognizes The Same Three Distinct Theories for Liability for Prescription Drugs.*

As a general matter, the Third Restatement, explains that "'strict products liability' is a term of art that reflects the judgment that products liability is a discrete area of tort law which borrows from both negligence and warranty. It is not fully congruent with classical tort or contract law." § 1, comment a. The Restatement goes on to identify and define the three now familiar rationales for liability: a product is "defective" if it has "a manufacturing defect, is defective in design, or is defective because of inadequate instructions." RESTATEMENT (THIRD) OF TORTS § 2. Necessarily, allegations of design defect and warning defect require "[s]ome sort of independent assessment of advantages and disadvantages, to which some attach the label 'risk-utility balancing' ...." *Id.*, cmt. a.

In addition to recognizing that design defect law in some states may impose liability regardless of the availability of an alternative design, the Third Restatement, in section 6, recognizes that possibility in

a section that addresses liability for "Prescription Drugs and Medical Devices" in particular. Section 6, like Section 2, identifies the three familiar categories of "defect" in prescription drugs. See § 6. Subsection 6(c) specifically addresses design defect claims:

> (c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

§ 6(c). *See also id.* at § 6(d) (providing a detailed definition of inadequate warnings). Notably, §6(c) nowhere suggests that a plaintiff is required to prove that a defendant manufacturer had available a reasonable alternative design.

The comments to § 6 are very instructive with respect to pre-emption as well. For instance, the Restatement acknowledges that prescription drugs are subject to federal regulation, but strongly cautions that "unqualified deference to these regulatory mechanisms is considered by a growing number of courts to be unjustified. An approved prescription drug or medical device can present significant risks without corresponding advantages." *Id.* at § 6, cmt. b.

The Restatement unmistakably adopts the position that, although the standard for establishing design defect liability for a prescription drug may be rigorous, the liability standard is analytically distinct from the questions whether government regulation immunizes a manufacturer from such liability or whether federal law pre-empts such state law tort

claims altogether. Put another way, § 6(c) sets a general liability standard for prescription drugs, while § 4 (discussed in Part IV.A.3. below) creates a possible "affirmative defense" available to manufacturers. But the question of federal pre-emption of state tort law is yet a separate question from either of these substantive tort law questions.

In sum, the Second and Third Restatements both expressly recognize the familiar distinction between design defect and inadequate warning claims multiple times. Indeed, the Restatements plainly explain that design defect and failure-to-warn claims rely on *different* facts and *distinct legal concepts*. Moreover, the Restatements make clear that warnings are not a legal substitute for providing a reasonably safe product, because an inadequate warning claim takes the product's underlying design as a given, and asks if the product could have been used safely with proper warnings. A design defect claim, by contrast, asks whether the product is unreasonably dangerous, applying a risk-utility analysis. DOBBS, at §§ 357-361; see *supra*, at 17-18.

Thus, it would be wrong as a matter of substantive tort law to assert that in general a design defect claim "reflects a duty to alter FDA-approved labeling deemed inadequate." U.S. Br. at 12. As the United States recognizes, traditional design defect claims do not hinge on the "adequacy of labeling," *id.*, and even the United States admits that "whether the FDCA would preempt" true design defect claims is a more "difficult and close" question than possible pre-emption of inadequate warning claims. *Id.*

3. Compliance with Government Regulations is at Most an Affirmative Defense, Not a Basis for Pre-Emption-Based Immunity.

Longstanding tort law could not be plainer in adopting the position that a defendant's compliance with statutory or regulatory safety regulations does not create legal immunity from harm caused by dangerous products. The Third Restatement § 4 makes clear that "a product's noncompliance with" such safety standards "renders the productive defective with respect to the risks sought to be reduced by the" standard. § 4(a). *Cf.* DOBBS, at 1033-34 ("Under the common law, the defendant's compliance with a statute is not in itself a defense to a negligence action." * * * The common law rule in products cases is the same—evidence of compliance with statute or regulation is relevant to judgments about the product's alleged [] defects and hence admissible but not by any means conclusive.").

Not surprisingly then, the Third Restatement, § 4(b), summarizes the traditional rule, uniformly embraced in the States, that "a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, *but such compliance does not preclude as a matter of law a finding of product defect.*" (emphasis added). That foundational tort law principle is readily explained by the common law's view that safety regulations at most create a *floor* for the conduct and care expected of defendants, not a *ceiling*. DOBBS, at 1034. "In addition, even if legislatures and regulatory agencies are not 'captured' by the industries they regulate, statutes and regulations may reflect the heavy influence of the regulated industry as much as judicious concerns with safety." *Id.*

In a related and important principle applicable in this case, the Restatement cautions that the "doctrine of preemption based on supremacy of federal law should be distinguished from the proposition that compliance with statutory and regulatory standards satisfies the state's requirement for product safety." RESTATEMENT (THIRD) OF TORTS, at § 6, cmt. b. In other words, traditional tort law expressly rejects the proposition that compliance with federal regulation, such as FDA regulation of prescription drugs, as a matter of law equates with either (1) federal pre-emption of longstanding state tort law or (2) a tacit legal immunity from potential state tort liability. *Cf. Williamson*, 131 S. Ct. at 1139 (it is wrong to "treat all [] federal standards as if they were maximum standards, eliminating the possibility that the federal agency seeks only to set forth a minimum standard potentially supplemented through state tort law.").

Petitioner and its *amici*, however, effectively argue in favor of just such a proposition, a notion that the States' traditional tort law and this Court's pre-emption cases reject. Importantly, "[f]ederal lawmaking culture is oriented to regulation, not to private tort rights. Only a few federal statutes create private tort claims for personal injury. In many instances when state tort rights are displaced, no new comparable federal tort right is substituted." DOBBS, at 1035. Instead, "the manufacturer is subjected to regulation without being subjected to liability," *id.*, a truly unjustified windfall.

B. Unlike this Case, *Kurns* Involved Field Pre-emption.

Petitioner's reliance upon *Kurns* not only errs as a matter of tort law but also hits a sour note in terms

of pre-emption doctrine. The substantive differences between design defect and inadequate warning claims was not determinative in *Kurns* because that case involved *only* a claim of field pre-emption. *See* 132 S. Ct. at 1266 ("We deal here only with the latter [type of pre-emption], so-called field pre-emption."). Thus, in *Kurns* it did not matter whether the claim was for design defects or inadequate warnings because, in either event, such claims were "directed at the equipment of locomotives," and within the "field" that Congress preempted. 132 S. Ct. at 1268.

In the context of prescription drugs, however, there is no claim to *field* pre-emption. Instead, under impossibility pre-emption analysis, the difference between the rationales for state tort liability may make all the difference. Furthermore, the Court in *Kurns* analyzed the products at issue — locomotive brakeshoes and boilers that contained asbestos insulation — under the Third Restatement's general products liability provision, §2(c), not under the specific provision for prescription drugs, §6, the latter of which emphasizes in the very context of this case the distinction between design defects and inadequate warning claims.

At the end of the day, there is no denying that design defect and inadequate warning claims are fundamentally different claims. As three Justices correctly observed in *Kurns*, "failure-to-warn claims proceed on a fundamentally different theory of tort liability [than design defect claims] that does not implicate a product's physical composition at all." 132 S. Ct. at 1272. Indeed, as was true in *Kurns*, in most if not all States, design defect and failure to warn are "'distinct cause[s] of action under the theory of strict

products liability.'" *Id.* (quoting *Riley v. American Honda Motor Co.*, 856 P.2d 196, 198 (Mont. 1993)).

Most importantly, in *Wyeth* the Court expressly recognized the difference, observing "that a failure-to-warn claim is 'narrower' than a claim that alleges a defect in the underlying product." *Kurns*, at 1273 (quoting *Wyeth*, 555 U.S. at 565). Indeed, in conducting its impossibility pre-emption analysis in *Wyeth*, the Court expressly distinguished between design defect and failure to warn claims. 555 U.S. at 565. The fact that *Kurns* found both design defect and failure-to-warn claims subject to field pre-emption in the context of that case in no way demonstrates that such claims are substantively identical. To the contrary, it could not be clearer that design defect and inadequate warning claims are distinct, as the Court expressly and correctly recognized in *Wyeth*.

V. DISMISSAL AS IMPROVIDENTLY GRANTED OR CERTIFICATION TO THE NEW HAMPSHIRE SUPREME COURT MAY BE WARRANTED HERE.

There is considerable argument in the parties' and the *amici curiae* briefs about exactly what New Hampshire law requires in order to establish tort liability for a prescription drug that causes harm. Moreover, the Solicitor General takes the position that New Hampshire law is in fact idiosyncratic so that this case does not actually present a "design defect" claim. U.S. Br. at 13. If the Court sees New Hampshire law as the Petitioner and its *amici* suggest, then the better course for the Court may be not to decide this case at all. *Cf. United States v. Shannon*, 342 U.S. 288, 294-95 (1952) (Frankfurter, J.) (the Court should dismiss because it became mani-

fest after argument that the cases "were legal sports. Neither is likely to recur; both are individualized instances...."); *New York v. Uplinger*, 467 U.S. 246, 249 n. 2 (1984) (*per curiam*) (dismissing in part because of uncertainty and confusion about underlying New York law); *Rescue Army v. Municipal Court*, 331 U.S. 549, 575 (1947) (dismissing where federal issue was presented "in highly abstract form" without the benefit of refinement of the relevant state law).[4]

At a minimum, the Court might consider seeking a definitive statement of New Hampshire law before deciding the pre-emption question. New Hampshire, like most states, permits certification. N.H. Sup. Ct. R. 34 ("This court may answer questions of law certified to it by the Supreme Court of the United States"). If the Court were to decide that the precise contours of New Hampshire tort law are determinative, or even very important, in deciding this case, then certification of those state law questions to the court with the authority to definitively answer them may be proper.

Certification can save "time, energy, and resources and helps build a cooperative judicial federalism." *Lehman Bros. v. Schein*, 416 U.S. 386, 391 (1974); *see also Arizonans for Official English v. Arizona*, 520 U.S. 43, 76 (1997) (certification "allows a federal court faced with a novel state-law question to put the question directly to the state's highest court, reducing the delay, cutting the cost, and increasing the assurance of gaining an authoritative response"); *cf.*

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[4] Further undermining the potential desirability of deciding this case is the recent representation of the United States that the "FDA is considering a regulatory change that *** [if] adopted, [] could eliminate preemption of failure-to-warn claims against generic-drug manufacturers." U.S. Br. at 15 n. 2.

Employment Div. v. Smith, 485 U.S. 660 (1988) (remanding to state court to answer question whether peyote use violated state law). The Court should be wary of trusting Petitioner's assertions about the bottom line of New Hampshire tort law; instead, the most reliable interpretation of New Hampshire tort law can only be given by that state's supreme court. Thus, this may be one of those infrequent cases in which certification by this Court of a crucial state law question is appropriate.

CONCLUSION

The judgment of the court of appeals should be affirmed.

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AMICUS CURIAE BRIEF

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Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,
v.
KAREN L. BARTLETT,
Respondent.

On Writ of Certiorari to the
United States Court of Appeals for the First Circuit

BRIEF OF *AMICUS CURIAE* DRI – THE VOICE OF THE DEFENSE BAR IN SUPPORT OF PETITIONER

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INTEREST OF THE *AMICUS CURIAE*[*]

Amicus curiae DRI–The Voice of the Defense Bar ("DRI") is an international membership organization of more than 23,000 attorneys engaged in the defense of clients in civil litigation. DRI is committed to enhancing the skills, effectiveness, and professionalism of defense attorneys in furtherance of their clients' interests. Because of this commitment, DRI seeks to address issues germane to defense attorneys and the civil justice system. DRI has long been a voice in the ongoing effort to make the civil justice system more fair, efficient, and consistent. To promote its objectives, DRI participates as *amicus curiae* in cases that raise issues of vital concern to its members, their clients, and the judicial system.

DRI members represent pharmaceutical manufacturers, distributors, wholesalers, and retailers in product-liability suits in state and federal courts around the country. Members have considerable familiarity with the interplay between state products liability law and the federal regulations that govern prescription drug marketing. Not only are members well versed in how prescription-drug cases are pleaded, briefed, and argued, they also witness first-hand how the parties' legal arguments are distilled into jury arguments

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[*] The parties' blanket consents to the filing of *amicus curiae* briefs are on file with the Clerk. No counsel for a party authored any part of this brief, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the brief's preparation or submission.

and presentations at trial. This experience has shown that prescription-drug product-liability trials are inevitably about a drug's warnings—what is in them, what is not in them, and how they have evolved over time.

DRI members are also very familiar with the challenges that arise when juries must evaluate complex decisions regarding the safety and efficacy of prescription drugs. For example, some evidence, such as anecdotal "adverse event" reports, tends to carry disproportionate weight with juries, compared with clinical-study evidence that may be more scientifically rigorous but less readily comprehensible to the layperson. This first-hand experience gives DRI a fuller understanding of the problems that would arise from allowing lay juries to second-guess the Food and Drug Administration ("FDA") on the core public-health decision of whether a particular drug should be available on the market.

SUMMARY OF ARGUMENT

A. There is no principled basis for distinguishing this case from *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011).

Like the plaintiff in *Mensing*, respondent asserted and argued below that a generic drug was defective—not in some abstract sense, but because the warnings it bore were inadequate to convey the risks that the drug's formulation entails. And like the defendants in *Mensing*, petitioner was prohibited by federal law from giving a different warning. Yet respondent now asserts that this case requires a different result because it was pleaded as a "design

defect" case (even though the plaintiff in *Mensing also* pleaded design defect).

It is worth noting what is not at issue in this case. It is undisputed that federal law prohibited petitioner from changing the design of its drug. A generic drug must be the "same as" a brand-name drug and its design cannot differ in any clinically relevant way. See 21 U.S.C. § 355(j)(2)(A). Any tort theory that would require a generic manufacturer to adopt an alternative design is plainly preempted because state law cannot mandate what federal law prohibits.

Indeed, alternative design in a drug product liability case is a legal fiction. As the court below readily recognized, there is no way to "alter a one-molecule drug." Pet. App. 10a. Further, if one were to alter a drug's molecular make-up, those alterations would result in a *different drug*, with *different clinical effects*, both in efficacy and in safety. See Bernard D. Goldstein & Mary Sue Henifin, "Reference Guide on Toxicology," at 664 n.82, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (Fed. Judicial Center 3d ed. 2011) ("[M]olecules with minor structural differences can produce very different biological effects.") (internal quotation marks omitted).

Thus, what this case truly comes down to is the drug's warnings. Indeed, product-liability cases against drug products invariably come down to the warnings. As the law, medical science, and common sense recognize, no drug is one-hundred percent safe. To the extent respondent now argues that this case is about something other than warnings, that argument is belied by the record, which shows that

the adequacy of sulindac's warnings was a central issue at trial, and the jury was instructed to consider their adequacy during deliberations. J.A. 514.

Respondent attempts to decouple this appeal from the record and argue that this case is not about sulindac's warnings, but instead is about whether sulindac belongs on the market at all. See, *e.g.*, Br. in Opp. 22-23. In other words, respondent contends that even if federal law prohibits state law from forcing petitioner to adopt a different label or a different design, it can force it to adopt *no* design whatsoever. The Eighth Circuit made the same error in *Mensing* v. *Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), which this Court reversed in *Mensing*. The Eighth Circuit had reasoned that generic drug defendants "could have simply stopped selling the product" to avoid being held liable for allegedly inadequate warnings federal law prevented them from changing. *Id.* at 611. This Court nonetheless held the tort claim preempted. As the court of appeals recognized (yet disregarded) in this case, accepting a "stop selling" theory would deprive *Mensing*'s holding of any effect, because "a generic maker can avoid defective warning lawsuits as well as design defect lawsuits by not making the drug at all." Pet. App. 11a; see also *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL No. 2226, 2012 WL 718618, at *3 (E.D. Ky. Mar. 5, 2012) ("And as the Generic Defendants observe, the idea that they should have simply stopped selling propoxyphene is an oversimplified solution that could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether.").

B. Even if respondent were advancing a theory truly independent of sulindac's warning and thus not squarely preempted under *Mensing*, she would fare no better. Respondent would allow a state jury to conduct its own balancing of risks and benefits, indistinguishable from the one FDA makes in approving a drug or declining to withdraw it from the market, and to expressly contradict FDA's judgment as to the outcome. That usurpation of FDA's role is preempted in its own right.

Congress gave FDA sole authority both to approve drugs for market *and to withdraw that approval*, and it erected substantive and procedural protections to guide that FDA decision-making process. The statutory framework does not allow state-court juries to second-guess FDA's judgment on the most fundamental question entrusted to that agency: which drugs shall be available to doctors and patients. Such "directly conflicting commands," *Wyeth* v. *Levine*, 555 U.S. 555, 590 (2009) (Thomas, J., concurring in the judgment), are preempted by federal law.

Even as respondent portrays it, therefore, the jury verdict in this case impossibly conflicts with federal law, replaces the expert judgment of an agency with the verdict of a lay jury, and endangers the health and safety of the American public.

C. Moreover, permitting this type of state-law tort claim to proceed despite FDA's sole authority over drug approval would put defendants at a serious disadvantage at trial. A claim focused on the mere act of selling an FDA-approved drug puts FDA's decision-making process on trial. Yet by virtue of federal law, generic drug manufacturers,

distributors, and retailers do not have access to all the studies performed and all the safety information reported on any one drug. Even brand-name drug manufacturers do not have access to the full scientific record relevant to a decision to maintain or withdraw a drug's approval; they are not privy to safety data on the universe of drugs plaintiffs inevitably argue would have been safer than the drug at issue. Yet federal law erects considerable barriers to private litigants that seek this information (and critical testimony) from the sole body with all the relevant data—FDA. Federal regulations requiring agency officials to refuse to comply with otherwise lawful third-party subpoenas thwart defendants' access to information critical to their defense.

ARGUMENT

The opinion below held petitioner liable for the design and labeling of its generic drug despite the court's recognition that under federal law petitioner could change neither. The court's decision thus is directly contrary to this Court's decision in *Mensing*. Indeed, even the First Circuit recognized that holding petitioner liable for the design of generic sulindac was inconsistent with the rationale of *Mensing* since it could no more "legally make sulindac in another composition" than change its labeling. Pet. App. 10a. The court of appeals' effort to distinguish *Mensing* as covering failure-to-warn but not design-defect claims is unpersuasive because products-liability cases involving pharmaceuticals inevitably turn on the adequacy of the warnings, as in fact occurred at trial. Respondent's effort to recast the jury's decision as simply a determination that

sulindac is defective because its risks outweigh its benefits, divorced from the warnings, is, as the opinion below correctly recognized, nothing but second-guessing FDA. The decision to approve, and also the decision to withdraw, a drug is committed to the expertise of FDA, under a prescribed standard and with procedural safeguards, and allowing a state-court jury to usurp FDA's role impossibly conflicts with federal law. Permitting juries to determine that a drug approved by FDA as safe and effective under prescribed conditions of use should not be available to physicians and their patients would undermine FDA's role and authority and endanger public health.

A. State-Law Design-Defect Cases Against Generic Drugs Invariably Turn on a Drug's Warnings and Are Preempted by Federal Law

Drugs come with warnings because no drug can be designed to be completely safe. Some drugs entail serious risks, including permanent, debilitating injuries, or even death. The chance of a particular class of persons experiencing an adverse effect from a drug can sometimes be predicted with some certainty, and therefore mitigated by warnings. Sometimes it is impossible to know who is at risk, only that the risk exists. In both situations, the information conveyed to doctors in warnings enables them to make informed judgments in the clinical setting as to whether the risks to a particular patient are or are not outweighed by the expected therapeutic benefits.

No drug molecule can be examined in a vacuum: under federal law, a drug is not a drug without

accompanying labeling, and the drug's formulation cannot be divorced from its labeling for tort-law purposes. Under the federal Food, Drug, and Cosmetic Act ("FDCA"), which governs drug approval, safety monitoring, and marketing withdrawal in the United States, applicants must submit proposed product labeling even to be considered for drug approval. See 21 U.S.C. § 355(b)(1)(F). And no drug may be approved for sale in the United States without an accompanying set of warnings. See 21 U.S.C. § 355(d). The labeling provides essential context—telling doctors what medical conditions a drug can treat, the effective dose, the types of patients who may benefit, the known risks, and how a doctor can minimize and monitor for those risks.

The same is true under state product-liability law: a drug is analyzed under a design-defect theory not based solely on the molecule, but also based on whether the labeling properly disclosed the known risks. That is because drugs are recognized as "unavoidably unsafe" products. Restatement (Second) of Torts § 402A, cmt. k (1965). The Restatement provides that

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

Id.

In DRI members' experience, under both federal and state law, drug safety is intertwined with a drug's labeling. DRI members are keenly aware from their trials across the country that whether based explicitly on a "failure-to-warn" theory or called simply "design defect," product-liability trials that involve pharmaceuticals inevitably sweep in the drug's warnings.

It should be no surprise, then, that the trial below—despite ostensibly being focused on a single theory of "defective design"—was not confined to a discussion of the molecular makeup of sulindac, but instead turned on whether sulindac's warnings adequately conveyed the risk of Stevens Johnson Syndrome ("SJS"). Respondent's experts disputed the adequacy of sulindac's FDA-approved warnings, see App. to Cert. Reply 6a-7a, 9a, 12a; J.A. 480, and the jury was charged with determining whether those warnings were adequate:

> If you determine that Sulindac was unreasonably dangerous and that a warning was not present and effective to avoid that unreasonable danger, then you must find [respondent] has proven this element of her claim, a defect in design. However, if you determine that Sulindac was unreasonably dangerous, but that a warning was present and effective to avoid that unreasonable danger, then you must find for [petitioner].

J.A. 514. As the jury instructions so pointedly show, the trial court held petitioner liable for selling a drug that a jury found to be unreasonably dangerous *as labeled*. That finding punishes petitioner for doing exactly what federal law required: giving its generic

drug the same labeling as the brand-name drug Clinoril®. See 21 U.S.C. § 355(j)(2)(A)(v).

As this Court recognized just two Terms ago, a generic drug defendant cannot be held liable under state law for giving an allegedly inadequate warning because federal law does not permit the company to take any unilateral step to minimize the drug's risks. *Mensing*, 131 S. Ct. at 2579. Thus, it cannot strengthen the warnings, clarify the population of patients who may benefit from the drug, or mandate, or even recommend, closer medical monitoring or registration. All these actions would require changes to the package insert or related warnings information (defined broadly as "labeling"), see 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(*l*)(2) (2012), none of which can be accomplished independently by a generic drug company. In other words, all the potential avenues the FDCA affords to drug manufacturers to minimize the risks of a drug while maintaining its place on the market were unavailable to petitioner.

The same conflict arises whether a plaintiff argues that a generic drug defendant should have (1) changed its warnings, (2) changed the design of its drug, or (3) simply stopped selling the product. *Mensing* confirms that the first two options are directly preempted by federal law. Federal law requires generic drugs to be the "same as" their brand-name counterparts, in both design and labeling. 21 U.S.C. § 355(j)(2)(A); see *Mensing*, 131 S. Ct. at 2575.

The third option—to "stop selling"—is no less invalid; it is no option at all. Such a theory asks a jury to find that, *at least absent some change in the*

FDA-approved labeling or design, the drug as currently designed and labeled may not be sold or used in that state without incurring liability. That still amounts to state-law punishment for the very features that, under federal law, the generic manufacturer is powerless to change: the labeling and the design. See *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, MDL No. 2243, 2011 WL 5903623, at *6 n.5 (D.N.J. Nov. 21, 2011) ("Plaintiffs insist that Generic Defendants could have simply removed [the drug] from the market. . . . [I]t is essentially a re-argument of *Mensing*. The Supreme Court unequivocally held that failure-to-warn claims against generic drug manufacturers are preempted by federal law.").

Contrary to the opinion below, *Mensing* was not just a case about claims pleaded as failure-to-warn. Mensing herself alleged—just like respondent argues here—that "defendants developed, marketed, and distributed," *i.e.*, *sold the drug*, "even after learning of the design and manufacturing defects." J.A., *PLIVA, Inc.* v. *Mensing*, No. 09-993, 2011 WL 1209890, at *106-113 (U.S. Jan. 24, 2011). The clear holding of *Mensing* is that punishing a manufacturer for selling a drug it had no opportunity to design or label differently places the manufacturer in an impossible position. The Supremacy Clause requires that the state-law rule must yield, whether the state demands that the manufacturer choose a different design or *no* design at all.

B. A State-Law Tort Regime That Permits Juries To Overrule FDA's Decision To Allow a Drug To Be Available to Doctors and Patients Is Not Permissible Under the Supremacy Clause

Even if respondent could successfully disentangle her tort claim from the plainly preempted design-defect and failure-to-warn theories on which the case was tried, her post-hoc "stop-selling" theory would still be preempted. Respondent maintains that the 50 states, or any of them, may ban the sale or use of any drug that they deem "unreasonably dangerous" on the ground that "the [drug's] risks outweigh its benefits." Br. in Opp. 22. The scheme respondent proposes is contrary to federal law. Under federal law, a single decision-maker decides whether a drug's risks outweigh its benefits: that is FDA, based on defined criteria, a fair process, and—above all—a capacity to understand the science at issue that far exceeds a lay jury's. When FDA approves a drug, it does not simply remove federal obstacles to its manufacture and marketing; rather, it decides that the drugs it approves shall be available to healthcare providers and their patients for the benefit of the public health. Under the system Congress created, FDA's judgment about safety and efficacy cannot be second-guessed by the States, or any one of them, or a jury in one of their courtrooms.

Furthermore, for a state to remove a generic equivalent to a branded drug that remains on the market would undermine the goals of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman"), Pub. L. No. 98-417, 98 Stat. 1585 (1984), which created the system that allows

generic drugs to be readily available at low cost to consumers. If petitioner were to stop selling generic sulindac, the reference-listed drug Clinoril® would remain available for sale in New Hampshire, and the net result would be only that consumers would pay more. The vital purpose of Hatch-Waxman, as this Court recognized in *Mensing*, was to allow "the generic drug market to expand, bringing more drugs more quickly and cheaply to the public." 131 S. Ct. at 2582. It is precisely for that purpose that Hatch-Waxman requires generic manufacturers to make their designs and labels the "same as" those of the brand drugs that FDA has already approved as safe and effective. 21 U.S.C. § 355(j)(2)(A). To permit juries, acting under state law, to find that a generic drug is unsafe and should not be sold because the manufacturer adheres to its federal duty of sameness under Hatch-Waxman would impermissibly conflict with Congress's objective to facilitate the availability of lower cost generic substitutes for previously approved brand drugs.

1. FDA Exercises Its Sole Power To Approve and Withdraw Drugs Based on Rigorous Procedures and Scientific Evidence

a. Congress vested in FDA the sole power to approve drugs for market and to remove them from the market. The FDCA expressly prohibits marketing a drug without FDA approval. See 21 U.S.C. § 331(d) (prohibiting "introduction or delivery for introduction into commerce of any article in violation of section . . . 355"); *id.* § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug" without FDA

approval); see also *id.* §§ 332, 333, 334 (severe penalties for marketing a drug without that approval). And even after it approves a drug, FDA retains the express and sole authority to *withdraw* a drug's approval. See 21 U.S.C. § 355(e); see also 21 C.F.R. § 314.150 (2012).

Congress prescribed precise standards and procedures for FDA to apply in making its approval and withdrawal decisions. FDA must decide within specified time periods whether the standard for approval of a new drug application is met, see 21 U.S.C. § 355(c)(1), and if so, that is the end of the matter: FDA "shall issue an order approving the application." *Id.* § 355(d). And it shall remain approved unless and until FDA concludes, generally "after due notice and opportunity for hearing," that the (distinct) statutory standard for withdrawing a drug is met. *Id.* § 355(e).

The FDCA requires that the decision to approve a drug be based on a careful balancing of its risks and benefits. This balancing is an important concept that underpins the Act's drug approval regime. Manufacturers must provide FDA with clinical data that a drug "is safe for use" *and* that it is "effective in use" to obtain marketing approval. 21 U.S.C. § 355(b)(1)(A). FDA is tasked with deciding whether the benefits of a drug outweigh its risks based on all readily ascertainable information about that drug and its effects on a particular class of patients under prescribed conditions of use. If a manufacturer does not provide "substantial evidence" that a drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," or if "there is a lack of substantial evidence

that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the proposed labeling," FDA may not approve that application. See 21 U.S.C. § 355(d)(1), (5).

The FDCA also specifies the level of scientific evidence required for FDA to approve a drug. Drug approval must be based on "substantial evidence." 21 U.S.C. § 355(d). The Act defines "substantial evidence" as

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

21 U.S.C. § 355(d)(7).

The decision to withdraw a drug from the market requires comparable scientific analysis and policy choices by FDA. See *Warner-Lambert Co.* v. *Heckler*, 787 F.2d 147, 151 (D.C. Cir. 1986) ("The statute mandates the same [substantial evidence] standard when the Commissioner is deciding whether to withdraw approval for a drug that previously received FDA approval."). Pursuant to the Act, FDA's withdrawal decision must be based on "clinical or other experience, tests, or other scientific data," and evaluated in conjunction with the "conditions of

use" on which the drug was approved. See 21 U.S.C. § 355(e). In other words, FDA must answer the question: Does the best science available counsel in favor of permitting a drug to be marketed, given what is known about its risks and benefits?

Critical to both the approval and withdrawal decision is the statutory phrase "conditions of use." No drug is safe for all people, for all purposes, for all time. Thus, when FDA approves a drug (or later reexamines its safety), it approves it only in conjunction with specific, approved labeling, which includes both warnings about risks and directions about which patients may benefit from the drug. See 21 U.S.C. § 355(b)(1)(F). As a result, any decision on the continued marketing of a drug cannot be made in isolation without considering (1) what has been done and what could be done to better educate physicians and patients about the particular risks of a drug, (2) which patients are most likely to benefit from a drug, (3) how much and how long a drug should be administered, and (4) how a physician and patient can best monitor the patient to ensure any adverse effects are caught early and properly addressed. *Cf.* 21 U.S.C. § 355-1(e), (f) (listing potential risk mitigation strategies such as direct-to-patient warnings, written informed consent forms, and medical monitoring).

b. Withdrawing a drug from the market is a serious decision that requires a close and unbiased look at the science and an eye to the broader public health. A decision to withdraw a drug's approval ends the ability of doctors to prescribe that drug for any patient under any condition. Accordingly, just as with the approval process, FDA does not exercise

its authority to *withdraw* a drug's approval in isolation. FDA convenes Advisory Committees at which leading scientists in the relevant fields hear testimony, discuss evidence, and make recommendations to the agency. FDA hears testimony not just from agency and company officials, but also from practicing clinicians, patient advocacy groups, and often patients themselves.

If the evidence demonstrates problems with an approved drug, FDA seeks solutions to minimize the risks of a drug short of withdrawing approval. People suffering from debilitating and life-threatening diseases may face limited options. There are some diseases for which only one or two drugs are approved. Some patients fail to respond to conventional therapies and require different drugs, which have a different risk profile. Some patients are allergic to drugs used as conventional therapies, and doctors must resort to second-line drugs. FDA places great reliance on doctors to use their best professional judgment to determine when a treatment, though of a higher risk, is nonetheless the right treatment for an individual. "All drugs have risks, and prescribers must balance the risks and benefits of a drug when making judgments about an individual patient's therapy." FDA, Draft Guidance for Industry on the FDA's "Drug Watch" for Emerging Drug Safety Information, 70 Fed. Reg. 24606, 24606 (May 10, 2005); see also FDA, Guidance on Drug Safety Information – FDA's Communication to the Public, 72 Fed. Reg. 10224, 10224 (Mar. 7, 2007) (implementing the draft guidance).

The FDCA gives FDA many options short of withdrawal to mitigate the risks of a drug without pulling it from the market. See 21 U.S.C. § 355-1(e), (f) (giving FDA authority, *inter alia*, to mandate new warnings, require that patients sign an informed consent, receive patient-focused literature on a drug, or view a video, and require registries for doctors and patients). For example, in 2008, FDA received a petition from an advocacy group requesting that FDA withdraw its approval for Avandia, a diabetes drug. FDA decided to maintain the drug's approval because its benefits outweighed its risks for a class of patients. But to mitigate the drug's risks, FDA implemented stricter procedures for prescribing and use, and required the manufacturer to complete an additional clinical trial on the drug. See Memorandum from Janet Woodcock, Director, Center for Drug Evaluation and Research, on Decision on continued marketing of rosiglitazone (Avandia, Avandamet, Avandaryl) (Sept. 22, 2010), available at http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM226959.pdf.

c. Despite the array of mechanisms FDA has to minimize the risks of a drug while keeping it available for those who benefit from it, in some cases scientific evidence develops and changes the risk/benefit profile of a drug. In those cases where a drug's benefits no longer outweigh its risks for a given indication, FDA exercises its authority to withdraw that drug's approval.

FDA's decision on whether to maintain the cancer drug Avastin's approval for metastatic breast cancer patients is a case in point, illustrating the vital role

FDA plays in balancing scientific data and public safety for critical decisions to deny access to a drug. On February 25, 2008, FDA granted accelerated approval to Avastin for use in certain advanced-stage breast cancer patients because of evidence that the drug stopped the progression of cancer in some patients for close to six months. See FDA, Proposal To Withdraw Approval for the Breast Cancer Indication for Bevacizumab, 76 Fed. Reg. 27332, 27333 (May 11, 2011). It granted accelerated approval on the condition that the manufacturer conduct certain additional clinical studies to determine to a greater degree whether the efficacy of the drug outweighed its potential risks. *Id.*

In July 2010, FDA convened a meeting of the Oncologic Drugs Advisory Committee to review results of those studies. Due to the members' assessment that it was not possible to predict which group of breast cancer patients would benefit from the drug, and given reports of severe side effects, the Advisory Committee recommended withdrawing Avastin's breast cancer indication. See Tr. for the Oncologic Drugs Advisory Committee (July 20, 2010), available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM221998.pdf. Several months later, the Office of Oncology Products at FDA announced its decision to withdraw the drug's approval for breast cancer patients, and FDA wrote a letter to the breast cancer community explaining its decision. See Letter from Janet Woodcock, FDA, to Breast Cancer Community (Dec. 16, 2012), available at www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM237286.pdf.

Avastin's manufacturer—and many patient advocacy groups—objected to FDA's decision, and the manufacturer requested an opportunity for a formal hearing. That hearing took place in June 2011 before the Oncologic Drugs Advisory Committee, and was presided over by an FDA representative. See Tr. of FDA Public Hearing on Proposal To Withdraw Approval for the Breast Cancer Indication for Bevacizumab (Avastin) [hereinafter "Tr. of Avastin Hr'g"] (June 28-29, 2011), available at http://www.fda.gov/downloads/NewsEvents/MeetingsConferencesWorkshops/UCM261611.pdf and http://www.fda.gov/downloads/NewsEvents/MeetingsConferencesWorkshops/UCM261697.pdf. The Advisory Committee was composed of medical experts from the M.D. Anderson Cancer Center in Houston, Texas, the Cleveland Clinic of Ohio, and the National Cancer Institute, a patient advocate representative, and a (non-voting) industry representative. Tr. of Avastin Hr'g 2-4 (June 28, 2011). Over two days, FDA and Avastin's manufacturer made statements and presented expert testimony through witnesses. FDA, the manufacturer, and the Advisory Committee were also given an opportunity to ask and respond to questions about the evidence. The hearing was also open to the public, and several dozen patients, doctors, and advocacy groups made statements about people whose breast cancer was unresponsive to all other conventional therapies yet remarkably responsive to Avastin. *Id.* at 19-124.

At the conclusion of the hearing, the Advisory Committee made a non-binding recommendation to FDA to withdraw approval. See Tr. of Avastin Hr'g 204-268 (June 29, 2011). The manufacturer and all interested parties then submitted written comments

to FDA. In November 2011, the FDA Commissioner issued her final decision to withdraw the breast cancer indication for Avastin. The Commissioner—in a seventy-page decision—recognized that there may be individuals who have benefited from Avastin, but found that due to the inability to reliably predict who those women are, and in combination with what she deemed "considerable" risks of the drug, the benefits of Avastin in combating breast cancer do not outweigh its risks for any identifiable population. See FDA, Decision of the Comm'r, Proposal to Withdraw Approval for Breast Cancer Indication for AVASTIN, Dkt. No. FDA-2010-N-0621, at 44-45, 48 (Nov. 18, 2011), available at http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0621-0544.

FDA did not withdraw Avastin from the market altogether. Rather, its decision took note of the fact that while Avastin was no longer FDA-approved for breast cancer, the drug would still be approved for other types of cancer—for which its benefits did outweigh its risks—and thus still on the market. *Id.* at 4.

As the Avastin example illustrates, FDA's decision whether to withdraw approval of a previously approved drug is a complex and nuanced determination, balancing many considerations beyond the ken of a lay jury, or the ability of private litigants to replicate.

2. The FDCA's Approval and Withdrawal Framework Does Not Allow State Juries To Declare an FDA-Approved Drug Unreasonably Dangerous

When the availability of a proven medicine is at stake, a single jury should not be making the decision for all. But allowing tort suits like the one below to proceed essentially permits just that outcome. Death by a thousand cuts, or a thousand jury verdicts, is still death. See *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 325 (2008) ("[E]xcluding common-law duties from the scope of pre-emption would make little sense. State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect."). And it is one that is prohibited by the FDCA, which places these decisions in the hands of FDA, an expert agency that—unlike a jury—has a national public-health responsibility and is politically accountable for its discharge of that responsibility.

FDA's rigorous withdrawal procedure, as illustrated by the Avastin example, stands in stark contrast to the process leading to the jury's determination in this case that sulindac as labeled should not have been sold. That jury was composed of lay persons, not experts. It heard evidence about sulindac, but not the full record before FDA. While it heard testimony from experts hired by counsel, it also heard the testimony of close to a dozen friends, family members, and caregivers of respondent, who all spoke about the effect of plaintiff's injuries. Not a single FDA official testified. After sitting in a

courtroom for three weeks, facing a single plaintiff with visible and severe injuries, the jury decided that sulindac (as labeled) should not have been sold.

Juries, unlike FDA, are not constrained by public health considerations, nor even by the standards that the FDCA requires of FDA upon approving a drug—and, critically for the purposes of this case, upon withdrawing that drug's approval. Juries, unlike FDA, do not have to weigh the risks and benefits of a drug in light of the conditions of use *and other options, if any, for all consumers of the drug*, as FDA must do. See 21 U.S.C. §§ 355(e)(1)-(3); 21 C.F.R. §§ 314.150(2)(i)-(iii) (2012). They do not have to read or analyze all the available scientific literature about a drug and defend their decision on appeal based on "substantial evidence" or even a review of the "whole record," as is required of FDA. 21 U.S.C. § 355(h); 5 U.S.C. § 556(d) (requiring agency adjudication to be based upon a review of the "whole record" and supported by "substantial evidence"). Juries do not have to convene hearings with FDA officials; in fact, they do not have to hear any testimony from FDA at all, as happened in this case. A jury must only listen to the evidence before it, look to a single, injured plaintiff and decide after-the-fact whether the drug should have been available for use by that plaintiff, whom the drug concededly injured. That is a stacked deck and does not result in wise public-health decisions.

That is not the system created by the FDCA. Allowing states to impose tort-law duties like the one upheld below conflicts with the careful statutory regime that Congress enacted to ensure that drugs that "substantial evidence" shows to be beneficial to

the public are available, and those that are not are either not approved, or withdrawn. See *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861, 886 (2000) (state-tort law may not declare unlawful an act that the responsible federal agency prescribed should remain lawful); *Wyeth*, 555 U.S. at 590 (Thomas, J., concurring in the judgment) ("[I]f federal law gives an individual the right to engage in certain behavior that state law prohibits," the state law is preempted, "notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior."); accord, *e.g.*, *Arizona* v. *United States*, 132 S. Ct. 2492, 2506-07 (2012) (holding that federal law prescribing that a decision "is entrusted to the discretion of the Federal Government" preempts state attempts to interfere with that discretion); *Chi. & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 324, 331 (1981) (reversing a decision "holding that a State can impose sanctions upon a regulated carrier for doing that which only the [federal agency], acting pursuant to the will of Congress, has the power to declare unlawful or unreasonable").

The FDCA answers the question Justice Breyer asked during oral argument in *Warner-Lambert Co.* v. *Kent*:

> Now, who would you rather have make the decision as to whether this drug is, on balance, going to save people or, on balance, going to hurt people? An expert agency, on the one hand, or 12 people pulled randomly for a jury role who see before them only the people whom the drug hurt and don't see those who need the drug to cure them? Now, it seems to

> me that is Congress's fundamental choice, and Congress has opted for the agency.

Tr. of Oral Arg. 30-31, *Warner-Lambert* (Feb. 25, 2008) (No. 06-1498). The FDCA entrusts that decision to FDA.

Individuals who believe that a drug's risk-benefit profile does not warrant marketing approval are not left without a remedy. They have an established pathway under federal law for pursuing a drug's withdrawal from the market. Consumers can—and regularly do—file Citizen's Petitions seeking a drug's withdrawal from the market. See 21 C.F.R. § 10.30 (2012) (providing process for citizens to petition FDA to "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action"). In response, FDA institutes comprehensive reviews of the scientific evidence and, at times, convenes Advisory Committees to consider issues presented by such petitions. FDA responds regularly to Citizen's Petitions seeking changes to a drug's warnings or seeking a drug's withdrawal, and FDA can and has withdrawn drug approvals in response to those petitions. See, *e.g.*, Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, to Sidney Wolfe, Director, Public Citizen's Health Research Group (Jan. 3, 2011), available at http://www.regulations.gov/#!documentDetail;D=FDA-2009-P-0595-0005 (granting petition to ban weight-loss drug Meridia, due to cardiovascular risks); FDA, Withdrawal of Approval of New Drug Application, 68 Fed. Reg. 1469, 1469 (Jan. 10, 2003) (announcing withdrawal of diabetes drug Rezulin's approval due to the introduction of new diabetes treatments with lower risk profiles).

The remedy given to citizens by the FDCA also prevents the practical and public-health problems raised by the 50-state drug-approval and withdrawal system that respondent envisions. From a public health standpoint, the Citizen's Petition process ensures that drugs that entail severe risks but nonetheless are important to make available to those patients who would benefit from them, remain an option for doctors to prescribe where appropriate. And FDA's uniform resolution of such petitions avoids the significant practical consequences of having a drug on sale in some states, but not others, due to unfavorable state-court verdicts (or even positive enactments). Such a legal patchwork would pose serious problems for drug companies seeking to avoid tort liability. For example, even if drug companies were able to prevent a drug from being sold within New Hampshire, no company can prevent a New Hampshire resident from filling his prescription across the river in Vermont (and then suing the company in New Hampshire). Allowing jury decisions that a drug is not safe enough to be marketed has the potential to bind large sections of the country, thereby nullifying the federal approval.

C. A Rule Permitting States To Put FDA's Approval Process on Trial Compromises Drug Defendants' Ability To Erect a Full Defense

Under the decision below, drug-defect litigation would proceed in a way that deprives FDA's expert judgment of even *evidentiary* effect, much less the conclusive effect that Congress intended it to have. If every state, and every state jury, were permitted to operate as a mini-FDA and to declare drugs

unsafe, pharmaceutical defendants would be left unable to draw on the views and actions of the *real* FDA to assert a robust defense to state-law tort actions.

The decision whether to approve or withdraw approval for a drug goes to the heart of federal drug regulation. At the center of that decision is FDA. State-tort lawsuits that assert a drug is defective inevitably put FDA's decision-making on trial.

Yet defendants are severely hamstrung in their ability to put on a full defense to these claims because the only party with full information is FDA—and FDA is not a party to a state-law product-liability action concerning a drug.

FDA is the only entity with all the data and other scientific information about a drug, and thus the only entity with the ability to conduct a true risk/benefit analysis on the continued marketing of a drug. It receives the full initial application to approve a new drug, an application that includes years of pre-clinical research, pharmacology profiles, animal studies, and the methodology and results for clinical studies. See 21 C.F.R. § 314.50 (2012). That application is not made public, and as a result, is only available to the initial applicant—and not later manufacturers of generic drugs (like petitioner), nor distributors of the drug, nor wholesalers. After the drug is on the market, FDA collects quarterly, annual, and periodic adverse event reports on the drug. See, *e.g.*, 21 C.F.R. §§ 312.85, 314.80, 314.81(b)(2)(i) (2012). FDA also has authority to order manufacturers to conduct new and follow-up studies to track certain safety issues. See 21 C.F.R. § 312.85 (2012). Most of this information is

unavailable to follow-on manufacturers of a drug, and other entities.

FDA is also the only entity that is charged with analyzing—and that has the ability to analyze—a drug in combination with other available drugs for a given subset of patients. Even a company that submits the original application to sell a new drug is missing this vital piece of information that is necessary to determine whether a drug should be on the market. The decision, as FDA readily acknowledges, cannot be made in a vacuum. See, *e.g.*, Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA, to Sidney Wolfe, Director, Public Citizen's Health Research Group, at 17 (Nov. 6, 2012), available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0455-0005 (denying a request from a consumer advocacy group to remove a high-dose Alzheimer's drug from the market, reasoning that it "is one of only two drugs indicated for treating the severe stage of" Alzheimer's and "a physician may determine that an improvement in a patient's cognition justifies the risk of additional side effects"). A drug with serious risks might remain on the market despite those risks because only one other, or perhaps no other, drug treats the disease that drug is designed to target. Only FDA can analyze the safety data of the drug at issue in litigation against the safety data of other drugs designed to treat the same disease, if any.

For example, there are dozens of different antibiotics on the market. A jury may see the variety of antibiotics available, and that a plaintiff was injured by one with a higher incidence of side

effects than, for example, penicillin. That jury may very well decide that the drug plaintiff took should never have been sold. However, when FDA examines that same drug, it may determine that it should be marketed because allergies may prevent a class of people from taking penicillin, or because that antibiotic has unique benefits such that some people who do not respond to other antibiotics are healed by that one. See *Riegel*, 552 U.S. at 325 ("A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.").

Given that FDA is at the center of the decision about a drug's efficacy and safety profile, it follows that FDA's analyses, conclusions, and underlying data are of primary relevance at a trial about whether a drug's benefits outweigh its risks. But for a drug manufacturer, there are serious roadblocks to accessing this information.

This Court has held that private litigants may not obtain testimony from federal employees simply by obtaining and serving a valid subpoena. See *U.S.* ex rel. *Touhy* v. *Ragen*, 340 U.S. 462 (1951). In *Touhy*, the Court held that the Department of Justice may lawfully promulgate regulations that restrict, or even prevent, private litigants from obtaining agency documents and/or testimony through otherwise valid subpoenas. Many other agencies, including FDA, have responded by promulgating comparable regulations of their own. For example, FDA regulations prohibit any FDA employee from giving "testimony before any tribunal pertaining to any function of the [FDA] or with respect to any information acquired in the discharge of his official

duties" without specific authorization from the Commissioner. 21 C.F.R. § 20.1(a) (2012). The Commissioner has asserted broad authority to grant or deny requests for testimony, based on her own conception of "the public interest" and "the objectives of the [FDCA] and [FDA]." *Id.* § 20.1(c) (2012). Even if an employee is lawfully subpoenaed, without the Commissioner's authorization, the employee can only "respectfully decline to testify on the grounds that it is prohibited." *Id.* § 20.1(b) (2012).

As a result, defendants who would benefit from FDA's considered expertise and far greater wealth of data on not just the drug at issue in a product-liability lawsuit, but the entire class of drugs considered along with that drug, are often blocked from obtaining FDA memoranda, internal meeting notes, and other indicia of the agency's reasoning for awarding and maintaining a drug's approval. Further, it is exceedingly rare when FDA permits an official to testify in a product-liability lawsuit about the internal agency decision-making process about any given drug.

These roadblocks to third-party discovery exist for sound policy reasons. FDA is not tasked with defending its approval decisions in state courts around the country; it is tasked with analyzing and monitoring the safety of drugs on the market. FDA has provided a procedural mechanism for individuals to challenge its decisions through filing Citizen's Petitions, of which there have been many (and some of which have led to a drug's withdrawal from market). But because the FDCA does not provide for state-tort actions challenging FDA drug approval decisions, it does not provide equivalent procedural

mechanisms to safeguard a defendant's ability to defend FDA's approval decision in court.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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Petitioner,

v.

KAREN L. BARTLETT,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF OF FORMER FDA COMMISSIONERS DR. DONALD KENNEDY AND DR. DAVID A. KESSLER AS AMICI CURIAE IN SUPPORT OF RESPONDENT

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BRIEF OF FORMER FDA COMMISSIONERS DR. DONALD KENNEDY AND DR. DAVID A. KESSLER AS AMICI CURIAE IN SUPPORT OF RESPONDENT

INTEREST OF AMICI CURIAE

This brief in support of respondent is filed on behalf of Dr. Donald Kennedy and Dr. David A. Kessler, each of whom served as Commissioner of Food and Drugs at the Food and Drug Administration (FDA).[1]

Dr. Donald Kennedy, a biologist, served as FDA Commissioner from 1977 to 1979. Dr. Kennedy then returned to Stanford University, where he had previously been a member of the faculty. From 1980 to 1992, Dr. Kennedy served as President of Stanford University. When he stepped down he returned to the faculty and is currently a professor emeritus. From 2000 until 2008, Dr. Kennedy also served as editor-in-chief of SCIENCE, the weekly magazine published by the American Association for the Advancement of Science. In 2010 he received Wonderfest's Carl Sagan Prize for Science Popularization.

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[1] Pursuant to Rule 37.6, amici state that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae or their counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

Dr. David A. Kessler was appointed by President George H.W. Bush in 1990 to serve as FDA Commissioner. Dr. Kessler was reappointed to that position by President William J. Clinton. After serving as Commissioner for seven years, Dr. Kessler left the FDA in 1997 to join the Yale School of Medicine as Dean, a position he held until 2003. From 2003 through 2007, Dr. Kessler served as Dean and Vice-Chancellor of the University of California, San Francisco, Medical School. Dr. Kessler remains on the medical school faculty. In 2009, he published THE END OF OVEREATING: TAKING CONTROL OF THE INSATIABLE AMERICAN APPETITE, and in 2012 he published YOUR FOOD IS FOOLING YOU: HOW YOUR BRAIN IS HIJACKED BY SUGAR, FAT, AND SALT.

Amici file this brief because the preemption position urged by petitioner threatens to undermine, not advance, the underlying goal of our nation's drug safety laws, which is "to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. 689, 696 (1948).

Amici previously expressed their views in a brief filed in *Wyeth v. Levine*, No. 06-1249, which was cited by the Court in its opinion. *See* 555 U.S. 55, 579 n.12 (2009). Both Dr. Kennedy and Dr. Kessler have also set forth their opinions in publications: Dr. Kennedy in an editorial, *Misbegotten Preemptions*, 320 SCIENCE 585 (May 2, 2008), and Dr. Kessler in a law review article, David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Effort to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461 (2008) (hereinafter "Kessler & Vladeck").

SUMMARY OF ARGUMENT

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* (FDCA), does not have the preemptive effect petitioner claims. The Act does not automatically bar state-law strict liability claims asserting that FDA-approved drugs are unreasonably dangerous for their approved uses. This conclusion applies to a drug approved via a "new drug application" (NDA), as well as to a generic version approved under an "abbreviated new drug application" (ANDA). *See* 21 U.S.C. §§ 355(a), (b) and (j).

The nation's drug safety laws have never placed the responsibility for drug safety solely on FDA. To the contrary, they place primary responsibility for safety squarely on the shoulders of drug manufacturers. To be sure, FDA also plays an important role. It oversees, and when necessary compels, compliance with safety standards. But the ultimate responsibility remains with the manufacturer. Amici submit that the preemption arguments pressed by petitioner and its amici turn that understanding upside down, improperly relieving manufacturers of front-line responsibility for the safety of their drugs and handing that job to FDA.

FDA does not have the resources or practical ability to serve as the sole guarantor of public safety and the statutory scheme has never operated under the assumption that FDA could successfully perform such a demanding role. The situation with respect to generics is no different. The Hatch-Waxman Amendments were not intended to compromise

public safety. Indeed, an important objective of the Amendments was to ensure that generics are just as safe as brand-name drugs, so that consumers will accept generics as substitutes, without worry that they are risking their health or their ability to seek compensation in the case of an injury.

In recent years, study after study has documented severe limitations in FDA's ability to ensure drug safety, as this Court recognized in *Wyeth v. Levine*, 555 U.S. 555, 578 n.11 (2009). The studies include:

- The Institute of Medicine of the National Academies, Ethical and Scientific Issues in Studying the Safety of Approved Drugs (May 2012);

- Institute of Medicine of the National Academies, The Future of Drug Safety: Promoting and Protecting, the Health of the Public (2007) ("IOM 2007 Report");

- FDA Science Board, FDA Science and Mission at Risk: A Report of the Subcommittee on Science and Technology (2007) ("FDA Science and Mission at Risk");

- GAO, Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process 5 (GAO–06–402, 2006), http:// www. gao. gov/ new. items/ d 06402. Pdf.

State tort litigation has always played an important role in ensuring that manufacturers bear responsibility for the safety of their drugs. Time and time again, such litigation has uncovered problems with long-term use of drugs, such as Vioxx, Bextra, Celebrex, Avandia, Rezulin, Baycol, Halcion, and

Zomax. State tort litigation preceded the enactment of the first federal drug safety law, the Federal Pure Food and Drug Act of 1906, and it has been a complement to federal enforcement of drug safety laws throughout the history of FDA and its predecessor agencies. Congress's unwillingness to cut off state tort claims is in keeping with FDA's longstanding judgment that this litigation supplements the agency's regulatory and enforcement activities. For decades, FDA consistently took the position that state tort claims were an important adjunct to federal regulation.

Congress has been particularly attentive to the federalism issues relating to FDA regulation of drugs and medical devices, but has never seen fit to preempt state damages actions against drug manufacturers. Congress has, over the years, provided limited preemption of state-law claims for medical devices specifically approved by FDA, over-the-counter drugs, and vaccines. Although Congress has repeatedly revisited the FDCA, including a significant overhaul in the 2007 Food and Drug Administration Amendments Act, Congress has never given drug companies the immunity from liability they now seek from this Court.

ARGUMENT

I. FDA IS NOT EQUIPPED TO SERVE AS THE SOLE GUARANTEE OF PUBLIC HEALTH.

The preemption arguments advanced by petitioner and its amici significantly overstate FDA's ability to police the marketplace on its own, without the backstop of state tort litigation. The question before this Court is whether state tort litigation jeopardizes the fulfillment of the FDCA's goal, namely, "to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S. at 696.

The short answer to that question is "no." State tort litigation plays an indispensable role in achieving the congressional goal. The fundamental problem FDA faces is that, by necessity, drugs are approved on the basis of less-than-perfect knowledge. The emergence of safety hazards that were unknown or not well understood at the time of a drug's approval is commonplace. FDA's approval process is not a warrant of the drug's absolute safety, but is an assessment of whether the drug's benefits outweigh its potential risks based on the evidence available to FDA at the time. As this Court has observed, "risk information [regarding pharmaceuticals] accumulates over time and that the same data may take on a different meaning in light of subsequent developments." *Wyeth v. Levine*, 555 U.S. 555, 569 (2009). This Court has also noted that "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new

risks emerge." *Id.* at 578-79. This Court's observations are correct, and they confirm that the federal regulatory process cannot serve as the sole guarantee of consumer safety.

A. The Approval Process For Both New Drugs And Generics Puts The Responsibility On The Manufacturer To Assure Safety.

To obtain approval for a new drug, a manufacturer must submit a new drug application (NDA) for the agency's review. 21 U.S.C. § 355; *see generally* Kessler & Vladeck, 96 GEO. L.J. 470-73. The NDA must include, among other things, full results of all clinical studies performed on human subjects. But risks that are rare, have long latency periods, result from drug interactions, or have adverse impacts on subpopulations often go undetected in clinical testing.

Pre-market human studies generally involve only a few thousand subjects and last only a year or so. Drugs are generally tested on no more than 600 to 3,000 patients prior to approval. *See* IOM 2007 Report, at 36. To control for conditions that might distort the study's findings, subjects who take other drugs or have other diseases or infirmities are excluded. *See* Kessler & Vladeck, 96 GEO. L.J. at 471. Because of these limitations, preapproval testing is generally incapable of detecting adverse effects that have long latency periods, result from drug interactions, occur infrequently, or affect sub-populations excluded from or not adequately represented in the clinical studies (for example, the elderly, ethnic minorities, and pregnant women). *Id.*

Moreover, FDA's assessment of risks-versus-benefits is generally done population-wide, not sub-group by sub-group, because there are rarely enough clinical trial participants in a sub-group to permit that degree of refined analysis. *Id.* As the IOM has commented:

> Preapproval trials typically are too small to detect even significant safety problems if they are rare. An adverse event (even a serious one) that occurs in less than one in 1,000 patients cannot be reliably detected except in the largest premarket trials but can pose a serious public health problem when hundreds of thousands or millions of people use the drug.

IOM 2007 Report at 37-38 (citations omitted).

For these reasons, FDA approval of a drug is no guarantee that the drug will not cause serious adverse effects even if properly used for its approved purposes. As the IOM explains, "FDA approval does not represent a lifetime guarantee of safety and efficacy," and drugs enter the U.S. market with "incomplete safety profiles." IOM 2007 Report at 2, 37. It is estimated that "as many as half of all new drugs have at least one serious adverse effect that is unknown at the time of drug approval."[2] An FDA historian has noted that "[i]n the years since 1962 literally thousands of prescription drug items have

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[2] Barbara J. Evans, *Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era*, 85 NOTRE DAME L. REV. 419, 430 (2010) (citing Bengt D. Furberg & Curt D. Furberg, EVALUATING CLINICAL RESEARCH 8 (2d ed. 2007)).

been taken off the U.S. market because they lacked evidence of safety and/or effectiveness, or they have had their labeling changed to reflect the known medical facts."[3] Professor and former FDA General Counsel Richard A. Merrill once quipped, "All consumers of prescription drugs serve as guinea pigs for the pharmaceutical industry."[4]

The situation with respect to generics is no different. Under the Hatch-Waxman Amendments, once a brand-name drug has been approved by FDA, any drug company may seek permission to market a generic version through a significantly simplified process, known as the abbreviated new drug application procedure, or ANDA Generic drug manufacturers must establish the generic drug's bioequivalence with the name brand drug. 21 U.S.C. § 355(j)(2)(A)(iv). The ANDA must also show that the "labeling proposed for the [generic] drug is the same as the labeling approved for" the brand-name drug. *Id.* at § 355(j)(2)(A)(v).

The Hatch-Waxman Amendments were not intended to compromise consumer safety. The House Energy and Commerce Committee Report cited "the policy objective" of the bill as "getting *safe* and *effective* generic substitutes on the market as quickly as possible after the expiration of the patent." H. Rep. No. 98-857, pt. 2, 98th Cong. 2d sess. 9 (1984)

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[3] Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA CONSUMER (June 1981), available at http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm.

[4] *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 20 (1973).

(emphasis added). The sponsors of the Amendments also stressed the pro-consumer nature of the bill. Rep. Waxman explained:

> The public will benefit twice; by the further incentive for research and development for new, innovative drugs and by the immediate reduction in drug prices when a generic is on the market as a competitor.

130 Cong. Rec. 24430 (Sept. 6, 1984) (statement of Rep. Waxman). Sen. Hatch added:

> This is a good bill. *Without compromising the public safety or welfare in the least* it will significantly lower the price of off-patent drugs, by many times in some cases, through increased generic competition.

Id. at 15847 (June 12, 1984) (statement of Sen. Hatch) (emphasis added).

The Hatch-Waxman Amendments are premised on the idea that consumers should be just as willing to accept generic pharmaceuticals as brand-name drugs. Consumers must have confidence that generics will be every bit as safe and effective as brand-name drugs, that manufacturers of generic drugs will be held to the same high standards as those of brand-name drugs, and that any violation of these standards can be addressed with an identical set of legal tools.

Manufacturers of generics retain the responsibility for assuring safety. Both brand-name and generic manufacturers are statutorily required to keep records of clinical experiences and ensure that their products remain safe and effective as

labeled. *See* 21 U.S.C. § 355(k). FDA regulations mandate that all manufacturers record and report adverse events. *See* 21 C.F.R. § 314.80(a) and (c) (brand-name manufacturers); 21 C.F.R. § 314.98(a) (generic manufacturers). Manufacturers must submit annual reports including, *inter alia*, a "summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product" and a "description of actions the applicant has taken or intends to take as a result of this new information." *Id.* at § 314.81(b)(2)(i).

In commentary accompanying FDA's implementation of the Hatch-Waxman Amendments, the agency repeated the manufacturer's responsibility:

> If an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.

57 Fed. Reg. 17950, 17961 cmt. 40 (Apr. 28, 1992).

At hearings on the Hatch-Waxman Amendments, representatives of the generic drug

industry stressed that they would keep FDA informed of the risks of their products.[5]

B. Practical Considerations Require That FDA Cannot Be The Sole Guarantor Of Consumer Safety.

FDA cannot singlehandedly perform the Herculean job of monitoring the safety of every one of the 11,000 or so drugs on the market. FDA does not have timely access to safety information and other resources to enable it to engage in a day-by-day monitoring of the safety profile of every one of the thousands of drugs on the market (not to mention medical devices, food products, blood products and other biologics, and the hundreds of other consumer products FDA regulates), let alone

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[5] *See New Drug Application*: Hearings on H.R. 3605, The Drug Price Competition Act, House Committee on Energy & Commerce, Subcommittee on Health and the Environment, 98th Cong., 1st sess. 45 (July 15, 1983) ("I, too, would like to comment on this adverse reaction issue that was brought up. I can speak as a manufacturer and for two other generic companies in whose representatives are in attendance that are sensitive to the importance of looking at adverse reactions. We are sensitive and responsible. The generic manufacturers of today will respond to those needs. As far as I know we have not been remiss in that responsibility. If it demands a higher level of knowledge on our part we are prepared to meet and respond to the need.") (testimony of Kenneth N. Larsen, chairman of the Generic Pharmaceutical Industry Association); *id.* at 50-51 ("[G]eneric companies . . . also put our money into research. Every single generic drug company that I know has a large research staff. It not only researches the drug that they are copying, or bringing into the market but it researches new drugs, researches adverse reaction.") (testimony of Mark Haddad, member of the board of directors of the Generic Pharmaceutical Industry Association).

the capacity to monitor the safety profile of an individual drug that is even remotely equivalent to that of the drug's manufacturer.

A long series of investigations and expert reports has documented the challenges that FDA faces. For example, the Institute of Medicine of the National Academies (IOM) recently concluded that "[t]he FDA's current approach to drug oversight in the post-marketing setting is not sufficiently systematic and does not ensure that it assesses the benefits and risks of drugs consistently over a drug's life cycle." Ethical and Scientific Issues in Studying the Safety of Approved Drugs (Report Brief) 3 (May 2012).

That finding echoed the conclusion of a 2007 IOM Report, which warned that FDA "lacks the resources to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future." IOM 2007 Report at 193. "[T]he existing regulatory framework is structured around the premarketing testing process; few tools are available for addressing postmarketing issues, short of the blunt instruments available to respond to clear-cut adulteration and misbranding." *Id.* at 153. *See also* GAO, Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process 5 (GAO–06–402, 2006), http:// www. gao. gov/ new. items/ d 06402. pdf ("FDA lacks a clear and effective process for making decisions about, and providing management oversight of, postmarket safety issues"); Efthimios Parasidis, *Patients over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WIS. L. REV. 929, 932 (2011) ("FDA epitomizes 'the hollow government syndrome—an agency with expanded

responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates.'") (quoting Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 431 (2008)).

Similarly, a report issued in November 2007 by a blue-ribbon advisory panel appointed by FDA concluded, "The scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the . . . regulatory system, and hence to the safety of the public." FDA Science and Mission at Risk, at § 1.1. The report found that the agency has "serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." *Id.* at 2-3.

As the FDA advisory panel observed, the agency's appropriations have not kept pace with its enormous and growing responsibilities. When the FDCA was enacted in 1938, Congress gave FDA a mandate "to review and approve prior to marketing, the safety of color additives, human food additives and animal feed additives, as well as to review and approve the safety and effectiveness of new human drugs, new animal drugs, human biological products and medical devices for human use." FDA Science and Mission at Risk, § 2.1. Since 1938, Congress has enacted "125 statutes that directly impact FDA's regulatory responsibilities," by requiring "the development of implementing regulations, guidance or other types of policy, and some require the establishment of entire new regulatory programs. Virtually all require some type of scientific

knowledge or expertise for the agency to address them." *Id.*

Despite the addition of all of these requirements, Congress did not provide "an appropriation of new personnel and increased funding designed to allow adequate implementation." *Id.* Indeed, during the past two decades, the agency's funding and staffing levels have remained static. For these and other reasons, the report concludes that "[t]his reality, combined with a burgeoning industry . . . has made it increasingly impossible for the FDA to maintain its historic public health mission." *Id.*

Although the Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) ("2007 FDCA Amendments") attempted to address the challenges facing FDA, the reforms under the Amendments will take considerable time to implement and their success is uncertain. *See* Kessler & Vladeck, 96 GEO. L.J. at 489-91. For example, a recent study in the British Medical Journal reported that, in 2009, only 22% of clinical-trial sponsors posted their results within one year of completion, as the 2007 FDCA Amendments require.[6] Although FDA has disputed that finding, it concedes that compliance is not complete.

The chief Senate sponsor of the 2007 FDCA Amendments explained that even a strengthened

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[6] Prayle, A. P., Hurley, M. N. & Smyth, A. R., *Compliance With Mandatory Reporting Of Clinical Trial Results On Clinicaltrials.Gov: Cross Sectional Study*, 344 BR. MED. J. d7373 (Jan. 3, 2012).

FDA should not be expected to assume exclusive responsibility for consumer safety:

> Clearly, the resources of the drug industry to collect and analyze post-market safety data vastly exceed the resources of the FDA, and no matter what we do, they will always have vastly greater resources to monitor the safety of their products than the FDA does. It is absurd to argue that the FDA, even with the enhanced resources and authorities provided by this legislation, commands the field when it comes to postmarket safety. The drug companies have the capacity to do a far more comprehensive job . . . [and] cannot be allowed to ignore their responsibilities and wait for the FDA to act.

153 Cong. Rec. S11832 (daily ed. Sept. 20, 2007) (remarks of Sen. Kennedy).

The bottom line is that FDA and manufacturers have highly unequal access to information about drug safety hazards. The annual revenues for a single prescription drug can be more than two hundred times the entire FDA budget dedicated to post-marketing surveillance for the same time period. *Id.* Manufacturers invariably obtain safety information before FDA and have access to a great deal of data that is not available to FDA.

The proof of the information imbalance between FDA and drug manufacturers is in the pudding. FDA has recently faced a flood of high-profile regulatory failures with approved drugs. For example, in 2007, eight years after FDA approval, the diabetes drug Avandia was found to increase the risk of heart

attacks.[7] In 2006, thirteen years after FDA approval, the medication Trasylol (used to reduce bleeding during surgery) was found to increase the risks of kidney failure, heart attack, and stroke.[8] And in 2004 and 2005, four and five years, respectively, after their initial approval, Cox-2 inhibitors[9] Bextra and Vioxx were withdrawn from the market after discovery that they increased the risks of heart attack and stroke and (in Bextra's case) serious skin reactions (such as SJS/TEN).[10] Millions of consumers were exposed to serious risks.[11] In the words of an FDA official, "Vioxx was [an] enormous national catastrophe. Up to 60,000 Americans, most over the

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[7] Steven E. Nissen, M.D. & Kathy Wolski, M.P.H., *Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes*, 356 NEW ENG. J.MED. 2457, 2458, 2467 (2007).

[8] Dennis T. Mangano, Ph.D., M.D., Iulia C. Tudor, Ph.D. & Cynthia Dietzel, M.D., *The Risk Associated with Aprotinin in Cardiac Surgery*, 354 NEW ENG. J. MED. 353, 361 (2006).

[9] Cox-2 inhibitors are a type of nonsteroidal anti-inflammatory drug (NSAID). *See, e.g.*, David J. Graham, M.D., M.P.H., *Cox-2 Inhibitors, Other NSAIDs, and Cardiovascular Risk: The Seduction of Common Sense*, 296 JAMA 1653, 1653 (2006).

[10] *Cox-2 Selective (includes Bextra, Celebrex, and Vioxx) and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm103420.htm.

[11] *See* Rodney Kristopher Miller, *Sacrificial Lambs: Compensating First Subscribers to FDA-Approved Medications for Postmarketing Injuries Resulting from Unlabeled Adverse Events*, 62 CATH. U. L. REV. (forthcoming) (available at SSRN: http://ssrn.com/abstract=2114394).

age of 50, died from Vioxx-related heart attacks . . . . Another 80,000 suffered nonfatal, but nonetheless life-threatening heart attacks."[12]

All of these examples demonstrate shortcomings in FDA regulation. In the case of Avandia, the danger was discovered not by FDA but by a third party's analysis of the publicly available data, and evidence suggests that the manufacturer had previously identified the cardiac risks at issue but did not disclose them to FDA.[13] Likewise, Trasylol's manufacturer withheld from FDA information pointing to a link between the drug and increased risk of stroke and heart attacks.[14] In the case of Vioxx, FDA did not understand the cardiovascular risks posed by the drug at the time of approval, and

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[12] *The Adequacy of FDA to Assure the Safety of the Nation's Drug Supply*: Hearings Before the Subcomm. on Oversight & Investigations of the H. Comm. On Energy & Commerce, 110 Cong. 59 (2007) (testimony of David J. Graham, M.D., M.P.H., Assoc. Dir., Science and Medicine, FDA Office of Surveillance and Epidemiology).

[13] Gardiner Harris, *Drug Maker Hid Test Data, Files Indicate*, N.Y. TIMES, July 13, 2010, at A1 ("The heart risks from Avandia first became public in May 2007, with a study from a cardiologist at the Cleveland Clinic who used data the company was forced by a lawsuit to post on its own Web site.").

[14] *Building a 21st Century FDA: Proposals to Improve Drug Safety and Innovation: Hearing Before the S. Comm. on Health, Educ., Labor, and Pensions*, 109 Cong. 41 (2006) (statement of Jim Guest, Pres. of Consumers Union) (noting that Trasylol's manufacturer, Bayer, "failed to inform the FDA Advisory Committee (which had convened 8 days earlier on September 21, 2006 to discuss Trasylol) of a new study that revealed an increased risk of death, serious kidney damage, congestive heart failure and stroke").

Merck withheld information relating to the drug's cardiovascular risks from FDA to avoid a stronger warning on the label.[15]

Congress is well aware of the limitations faced by FDA. Congressional hearings and reports have documented that FDA's resources are not commensurate with the agency's enormous task.[16]

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[15] *See* Thomas O. McGarity, THE PREEMPTION WAR 1-17 (2008) (detailing Vioxx's regulatory history); *McDarby v. Merck*, 949 A.2d 223, 231-47 (N.J. App. Div. 2008) (same); *see also Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry*: S. Hearing Before the Special Comm. on Aging, 110th Cong. 50 (2007) (testimony of Peter Lurie, M.D., M.P.H., Deputy Dir. of Public Citizen's Health Research Group, Wash. D.C.) (noting publication of incomplete trial data on Celebrex by the drug's manufacturer, Pfizer, "because [Pfizer] knew that the full data set that it had in its possession didn't show the benefit that half the data set showed").

[16] *See, e.g.*, *Should FDA Drug and Medical Device Regulation Bar State Liability Claims?* Hearing Before the House Committee on Oversight and Government Reform, 110th Cong. 2d Sess. (May 14, 2008) ("*House FDA Preemption Hearing*"); *Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?* Hearing Before the Senate Committee on the Judiciary, 110th Cong. 1st Sess. (Sept. 12, 2007); *Risk and Responsibility: The Roles of the FDA and Pharmaceutical Companies in Ensuring Safety of Approved Drugs, Like Vioxx: Hearing Before the House Comm. on Government Reform*, 109th Cong. (2005); *FDA's Drug Approval Process: Up to the Challenge?: Hearing Before the Senate Comm. on Health, Educ., Labor and Pensions*, 109th Cong. (2005); *FDA, Merck and Vioxx: Putting Patient Safety First?: Hearing Before the Senate Comm. on Finance*, 108th Cong. (2004); U.S. GOV'T ACCOUNTABILITY OFFICE, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 10, *available at* www.gao.gov/cgi-bin/getrpt?GAO-06-402.

Hearings have also confirmed the importance of state tort litigation. For example, Gregory Curfman, executive editor of the New England Journal of Medicine, warned that "preemption of common-law tort actions against drug and medical device companies is ill advised and will result in less safe medical products for the American people." *House FDA Preemption Hearing* (testimony of Dr. Curfman). Another expert advised a House Committee that:

> Preempting lawsuits against pharmaceutical manufacturers would remove a check on pharmaceutical manufacturers that is essential to prescription drug safety and the public health. Without the possibility of litigation against manufacturers and their executives, we are likely to see greater misrepresentation of safety-related data and more inappropriate use of potentially harmful medications.

Id. (testimony of Aaron S. Kesselheim, Brigham & Women's Hospital and Harvard Medical School).

Experience and practical considerations demonstrate that FDA cannot be the sole guarantor of consumer safety.

II. THE STATUTORY FRAMEWORK AND HISTORY SHOWS THAT THE FDA'S ROLE IN ENSURING SAFETY IS NOT EXCLUSIVE.

In *Wyeth v. Levine*, this Court observed that "Congress enacted the FDCA to bolster consumer protection against harmful products" and "did not

provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers." 555 U.S. at 574. "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70–year history." *Id.* "Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575.

This Court's observations were correct, and they compel affirmance of the judgment below. Indeed, it is telling that following this Court's decision in *Wyeth v. Levine*, FDA's analysis of "post marketing reports of severe tissue injury" with respect to promethazine (the generic form of Phenergan) led it to require a boxed warning of the adverse event that afflicted Diana Levine – the plaintiff in that case.[17] Hence, the very state tort suit that this Court

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[17] *See* FDA, *Information for Healthcare Professionals Intravenous Promethazine and Severe Tissue Injury, Including Gangrene*, http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm182169.htm (Sept. 16, 2009) (explaining that "FDA is requiring manufacturers of these products to revise the labeling for promethazine, including addition of a Boxed Warning describing the risk of severe tissue injury, including gangrene, requiring amputation following intravenous administration of promethazine").

addressed in 2009 demonstrates that state claims complement federal regulation.

A. The History of the FDCA Confirms That It Does Not Have The Preemptive Effect Petitioner Claims.

Federal drug labeling regulation began with the Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), codified at 21 U.S.C. §§ 1-15 (1934) (repealed in 1938 by 21 U.S.C. § 329(a)). Prior to 1906, "the States provided the primary and possibly the exclusive source of regulatory control over the labeling of foods and drugs." *In re Vioxx Prods. Liab. Litig.*, 501 F. Supp. 2d 776, 782 (E.D. La. 2007). State courts recognized common-law causes of action for consumers injured by medicines and related products.[18]

Nothing in the Pure Food and Drug Act of 1906 displaced traditional state-law tort remedies. The Act was part of the progressive agenda of the trust-busting reformer, Theodore Roosevelt,[19] and it was intended solely to protect consumers – not to deny

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[18] *See, e.g.*, *Boyd v. Coca Cola Bottling Works*, 177 S.W. 80, 81 (Tenn.1915); *Willson v. Faxon, Williams & Faxon*, 208 N.Y. 108, 112, 101 N.E. 799, 801 (1913); *Blood Balm Co. v. Cooper*, 83 Ga. 457, 10 S.E. 118, 119 (1889); *Thomas v. Winchester*, 2 Seld. 397, 1852 WL 4748 (N.Y.1852); *Fleet v. Hollenkemp*, 52 Ky. (1 B. Mon.) 219, 220 (1852).

[19] *See* Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, § 3, 34 Stat. 768, 768–69, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, § 201(d), 52 Stat. 1040, 1040 (codified in scattered sections of 21 U.S.C.).

state tort remedies to victims of unsafe drugs.[20] For example, in 1913, this Court considered the effect of a Wisconsin statute providing that mixtures or syrups offered for sale "shall have upon them no designation or brand . . . other than that required by the state law." *McDermott v. Wisconsin*, 228 U.S. 115, 127 (1913). Although this Court held that Wisconsin could not require that federally approved labels "shall be removed from the packages," the Court also "[c]onced[ed] to the state the authority to make regulations consistent with the Federal law for the further protection of its citizens against impure and misbranded food and drugs." *Id.* at 133.

The history of federal food and drug regulation has been an evolutionary process, in which existing (and sometimes longstanding) remedies have been removed from the market as new knowledge reveals health risks or other problems associated with them. For example, mercury, lead salts, arsenic, strychnine, and many other substances were once all regarded as widely useful therapies but are now considered obsolete.[21]

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[20] Dennis R. Johnson, *The History of the 1906 Pure Food and Drugs Act and the Meat Inspection Act*, 37 FOOD DRUG COSM. L.J. 5, 8–9 (1982); Richard Curtis Litman & Donald Saunders Litman, *Protection of the American Consumer: The Muckrakers and the Enactment of the First Federal Food and Drug Law in the United States*, 36 FOOD DRUG COSM. L.J. 647, 648–51 (1981).

[21] *See* John Fry, *Therapeutic Habits & Customs*, 56 PROCEEDINGS OF THE ROYALTY SOC'Y OF MEDICINE 127, 127-29 (1963).

In 1938, after the deaths of more than 100 people from elixir of sulfanilamide, Congress enacted the FDCA, which prohibited false therapeutic claims and for the first time required FDA premarket notification for drugs, although it did not impose a prescription requirement.[22] As this Court has long recognized, the purpose of the statute was to increase consumer protection. *See United States v. Dotterweich*, 320 U.S. 277, 280, 282 (1943) ("The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection").

Congress considered including in the FDCA a private federal cause of action for damages caused by faulty or unsafe products. *See* H.R. Rep. No. 73-6110, pt. 1, § 25 (1933) ("Liability for Personal Injuries - a right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this Act."). As this Court noted in *Wyeth v. Levine*, 555 U.S. at 574 n.7, the Senate deleted this proposed private cause of action from the bill on

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[22] Not until 1951 did Congress impose the familiar requirement that "prescription drugs be dispensed only upon a physician's prescription." *Christopher v. SmithKline Beecham Corp.*, 132 S.Ct. 2156, 2163 (2012). As originally enacted in 1938, the FDCA allowed manufacturers to designate certain drugs as prescription only, but it did not provide which drugs were to be sold by prescription. *Id.* at 2163 n1. Prior to Congress' enactment of the FDCA, a prescription was not needed to obtain any drug other than certain narcotics. *Id.*

the ground that it was unnecessary because "[a] common-law right of action exists" under state law.[23]

Congress has never seen fit to enact a preemption provision with respect to drugs. Indeed, Congress explicitly declined to do so in the 1962 amendments to the FDCA, which require FDA to ensure that a drug is effective as well as safe before the drug is approved. The purpose of the legislation was "to strengthen and broaden existing laws in the drug field so as to bring about better, safer, medicine and to establish a more effective system of enforcement of the drug laws." S. Rep. No. 87-1744, 87th Cong., 2d Sess. 1 (1962). The catalyst of the reforms was the thalidomide tragedy in Europe in the late 1950s and early 1960s, in which thousands of children were born with birth defects. *See* IOM 2007 Report, at 22, 152. In the 1962 Amendments, Congress made clear its intent not to preempt claims relying on state common law: "Nothing in the amendments . . . shall be construed as invalidating any provision of State law which would be valid in

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[23] Hearing on S. 1944 Before a Subcomm. of the Comm. on Commerce, 73d Cong., 2d Sess. 400, 403 (1933). *See also Consumer Fed'n of Am. v. Upjohn*, 346 A.2d 725 (D.C. 1975) (explaining that private right of action was omitted from bill because "it would create an *unnecessary* federal action *duplicative of state remedies*" and concluding that Congress "*rejected* [] setting up a nationally uniform law for such" actions) (emphasis added); Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 924 & n.130 (1994) ("Congress rejected a provision in a draft of the original FD&C Act providing a federal cause of action for damages [for injuries caused by prescription drugs] because 'a common law right of action [already] exists.'").

the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962, Pub. L. 87-781, § 202, 76 Stat. 780, 793.[24]

Congress' assumption that state-law causes of action would remain under the FDCA – coupled with its decision not to provide a federal remedy – is strong evidence that it did not mean to displace traditional state tort actions. Where Congress displaces state law, it typically provides an alternative federal remedy.[25] As the Court has acknowledged, "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates v. Dow Agrosciences LLC,*

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[24] The provision's language underscores Congress's judgment not to displace state product liability law, but to preserve it. *See California Federal Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 283 n.12 (1987) (explaining antipreemption thrust of phrase "a direct and positive conflict"); *Swift & Co. v. Wickham*, 382 U.S. 111, 132 n.3 (1965) (Douglas, J., dissenting) (same). The provision explicitly displaces only positive state law only where there is "a direct and positive conflict" between the FDCA's new effectiveness requirements and state law. Congress refrained from using broader language that might encompass other types of state law, such as tort law.

[25] *See, e.g.*, 42 U.S.C. § 2210 (Price-Anderson Act); 42 U.S.C. §§ 300aa-10 to 300aa-34 (National Vaccine Injury Compensation Program); 49 U.S.C. § 40101 (Supp. 2004) (Air Transportation Safety and System Stabilization Act of 2001, also known as the September 11th Victim Compensation Fund); 29 U.S.C. § 1144 (Employee Retirement Income Security Act of 1974).

544 U.S. 431, 449 (2005). *See also Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("This silence [of Congress in enacting and amending the Atomic Energy Act] takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

B. Congress Confirmed Its Understanding In a Series of Amendments To The FDCA.

When Congress has wished to preempt state law in the FDCA, it has done so explicitly. For example, in 1976, Congress enacted an express preemption provision for medical devices. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (considering the effect of the express preemption provision of the Medical Device Amendments of 1976, 21 U.S.C. § 360(k)(a)). As this Court opined in *Riegel*, "Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices." *Id.* at 327.

In addition, in the National Vaccine Injury Compensation Program ("VICP"), Congress provided an administrative remedy for vaccine-related injuries as an alternative to state tort liability, with the possibility of an opt-out to state court if the injured person wishes to pursue a state-law products liability remedy. 42 U.S.C. § 300aa-21(a). VCIP includes a specific provision that "[n]o vaccine manufacturer shall be liable in a civil action for

damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side-effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." *Id.* at § 300aa–22(b)(1).

In *Bruesewitz v. Wyeth*, 131 S. Ct. 1068 (2011), this Court held that the statutory language of the VCIP preempts design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects. But if there were no potential for non-warning claims against manufacturers of prescription drugs in the first place, there would have been no need for this Court's decision in *Bruesewitz*. Vaccines are approved under the Public Health Service Act, 42 U.S.C. § 300aa-1 to -6, but otherwise regulated as drugs. *E.g.*, 21 C.F.R. § 600 *et seq.* The regulatory treatment of vaccines thus confirms Congress' understanding that FDA regulation of a drug does not preempt state-law tort liability.

Further confirming the absence of preemption in this case are the express *anti*-preemption provisions for nonprescription or "over-the-counter" ("OTC") drugs, FDCA Section 751, 21 U.S.C. § 379r, and for the labeling and packaging of cosmetics, FDCA Section 752, 21 U.S.C. § 379s. These provisions prohibit any State or political subdivision from establishing or continuing "any requirement" relating to the regulation of an OTC drug or the labeling or packaging of a cosmetic that is "different from or in addition to, or that is otherwise not

identical with," a requirement under the FDCA, the Poison Prevention Packaging Act of 1970, 15 U.S.C. § 1471 *et seq.*, or the Fair Packaging and Labeling Act, 15 U.S.C. § 1451 *et seq.* *See* 21 U.S.C. § 379r(a), 379s(a). However, the OTC and cosmetic anti-preemption provisions expressly exempt state product liability actions from federal displacement: "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 379r(e), 379s(e).

Thus, although Congress has provided for some degree of preemption for state requirements regarding OTC drugs and cosmetics labeling, it has also specifically preserved state-law products liability, at least in part. The statutory framework demonstrates Congress' clear understanding of the potential for state-law products liability actions against manufacturers of OTC drugs, and cosmetics. The absence of any analogous express preemption provision for prescription drugs is significant. If Congress had wanted to take the extraordinary step of according drug manufacturers immunity from personal tort actions, it would have done so expressly. As this Court opined in *Wyeth v. Levine*, "Congress has repeatedly declined to pre-empt state law," and "Congress did not regard state tort litigation as an obstacle to achieving its purposes." 555 U.S. at 575, 581.

Moreover, the relationship between OTC and prescription drugs makes the lack of an express preemption provision for prescription drugs even more significant. Some OTC drugs are initially approved as prescription drugs under the FDCA and

are "switched over" to OTC status after several years of marketing, as in the cases of Claritin and Zyrtec. Thus, a drug initially receiving FDA approval may later become an OTC drug governed by Section 751, which explicitly contemplates products liability claims under state law. It is implausible to suggest that Congress silently created immunity through federal preemption for prescription-drug-related claims but then affirmatively negated that immunity when the same drug became OTC. Rather, it is plain that Congress has always assumed that the fact of FDA approval would not preclude state-law product liability actions.

Other provisions of the FDCA also acknowledge Congress' understanding of the potential for state tort liability. For example, Section 756 of the FDCA provides that certain safety reports to FDA may not be considered admissions for liability purposes. *See* 21 U.S.C. § 379v (manufacturer's submission of a safety or adverse event report is not "an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness"). This provision indicates a congressional recognition of the potential for state tort suits, because it's evident purpose is to prohibit the use of safety reports in product liability litigation.

The same view of non-preemption is reflected in the 2007 FDCA Amendments, Pub. L. No. 110-85, 121 Stat. 823 (2007). The Amendments do not contain any express preemption provision barring state-law damages claims. The sole preemption language included in the Amendments precludes

states and their political subdivisions from "establish[ing] or continu[ing] in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database." 42 U.S.C. § 282(d).

Given the statutory structure, courts have long held that FDA approval does not preempt design-defect claims. *See, e.g.*, *Riegel*, 552 U.S. at 340 n.11 & 343 n.16 (Ginsburg, J., dissenting) (collecting cases); *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 390-91 (7th Cir. 2010) ("Until the early 2000s, prescription drug companies infrequently invoked the preemption defense, and when they did, it rarely succeeded."); *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 537-38 (6th Cir. 1993) ("We reject the argument that FDA approval preempts state product liability claims based on design defect.") (citing *Hurley v. Lederle Lab. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176-77 (5th Cir. 1988)).

Of course, some courts have declined, as a matter of state law, to recognize strict-liability claims based on the design of a prescription drug.[26] Those states' courts have taken the view that prescription drugs are, by definition, "unavoidably

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[26] *See, e.g.*, *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003); *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996); *Martin v. Hacker*, 628 N.E.2d 1308 (N.Y. 1993); *Brown v. Superior Court*, 751 P.2d 470, 482-83 (Cal. 1988); *Edwards v. Basel Pharm.*, 933 P.2d 298, 300 (Okla.1997); *Wimbush v. Wyeth*, 619 F.3d 632 (6th Cir. 2010) (Ohio law); *Tatum v. Schering Corp.*, 795 F.2d 925, 926 (11th Cir. 1986) (Alabama law); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 658 (D. Md. 2011) (Maryland law).

unsafe" within the meaning of Restatement (Second) of Torts § 402A cmt. k (1965).[27] But the decision by some states not to recognize design-defect claims for prescription drugs hardly militates in favor of a finding of preemption. The longstanding assumption of the federal regulatory scheme, and judicial interpretations under it, is that the FDCA does not displace state tort actions. A state's choice to interpret its own tort law in a particular manner demonstrates that state law has a role to play with respect to approved drugs.

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[27] *See Bruesewitz*, 131 S. Ct. at 1077 n.41 (noting that, as of 1986, "a large number of courts" took comment k to mean that manufacturers "did not face strict liability for side effects of properly manufactured prescription drugs that were accompanied by adequate warnings"); *Kurns v. Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1268 (2012) (discussing Restatement (Third) of Torts: Products Liability § 2(c), at 14 (1998) (Third Restatement)). In general, comment k does not entail a categorical pronouncement that a particular product is unavoidably unsafe in all circumstances. *See* Nitin Shah, Note, *When Injury Is Unavoidable: The Vaccine Act's Limited Preemption Of Design Defect Claims*, 96 VA. L. REV. 199, 235 (2010) ("The longstanding majority approach is to analyze Comment k's applicability on a case-by-case basis."); AM. L. PRODS. LIAB. 3d § 17:47 (1987) ("Most courts have stated that there is no justification for giving all prescription drug manufacturers blanket immunity from strict liability under Comment k, and that whether a particular drug is unavoidably unsafe should be determined on a case-by-case basis.").

C. The FDA's Longstanding Position Recognized That The FDCA Does Not Have The Preemptive Effect Petitioner Claims.

As this Court opined in *Wyeth v. Levine*, "[i]n keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation." 555 U.S. at 578. "State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information." *Id.* at 579. "Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.*

In 1974, for example, FDA adopted a regulation providing for confidential treatment of any identifying information relating to physicians (and other health care professionals) included in adverse drug reaction reports (ADRs) submitted by the manufacturer to the FDA. 21 C.F.R. § 314.80(h). FDA adopted this regulation precisely because it recognized that federal law permits products liability lawsuits in which plaintiffs' counsel would seek such identifying data:

> Large numbers of requests are received from plaintiff's attorneys in product liability lawsuits, requesting records relating to any other injuries caused by the product that is the subject of the lawsuit.

39 Fed. Reg. 44629 (Dec. 24, 1974).

In a 1979 preamble accompanying a drug rule, the agency explained that state tort law does not interfere with federal regulation: "It is not the intent of the FDA to influence the civil tort liability of the manufacturer." 44 Fed. Reg. at 37437 (1979).

Similarly, in a 1998 Final Rule relating to labeling provided directly to patients for certain prescription drugs and other biological products, the FDA indicated that state tort law did not interfere with its regulations:

> Tort liability cannot be a major consideration for FDA which must be guided by the basic principles and requirements of the act in its regulatory activities. Nevertheless, FDA does not believe this rule would adversely affect civil tort liability....
>
> * * *
>
> FDA does not believe that the evolution of state tort law will cause the developments of standards that would be at odds with the agency's regulations.

63 Fed. Reg. 66378, 66384 (1998).

In 1997, a former chief counsel of the FDA explained that this Court's no-preemption ruling in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), was

consistent with the FDA's "longstanding ... presumption against preemption." Margaret Jane Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 FOOD & DRUG L.J. 7, 10 (1997). She added that:

> Given the harsh implications of foreclosing all judicial recourse for consumers injured by defective medical devices, FDA does not believe that Congress intended to effect so sweeping change without even a comment. Rather, the agency believes that Congress intended to restrict preemption to positive enactments (for example, legislation or regulations) that apply to the marketing of medical devices within a state, and did not intend to preempt state tort remedies for injury to individual consumers.

Id. at 9. Although the article concerned medical devices specifically rather than pharmaceuticals, its explanation of FDA's longstanding view of limited preemption applies *a fortiori* with respect to drugs.

In December 2000, the FDA proposed a new regulation to address the form and content of drug labeling, the principal purpose of which was to require a "Highlights" section on drug labels. At that time, the agency explained that "this proposed rule does not preempt state law," and "FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." 65 Fed. Reg. 81082, 81103 (2000).

Both FDA and Congress have long rejected the preemption position of petitioner and its amici. FDA is not the sole guarantor of public safety.

CONCLUSION

The judgment below should be affirmed.

Respectfully submitted.

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AMICUS CURIAE BRIEF

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AND
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No. 12-142

In the Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF THE GENERIC PHARMACEUTICAL ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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INTEREST OF THE AMICUS CURIAE[1]

The Generic Pharmaceutical Association ("GPhA") files this brief in support of petitioner Mutual Pharmaceutical Company, Inc., and in support of reversal of the United States Court of Appeals for the First Circuit's decision upholding the jury verdict against Mutual.

GPhA is a voluntary, non-profit association comprised of more than 70 manufacturers and distributors involved in the generic pharmaceutical industry. GPhA's members provide American consumers with generic medications that are as safe and effective as their brand-name counterparts, but at a fraction of the cost. "All generic drugs approved by [the Food and Drug Administration ("FDA")] have the same high quality, strength, purity, and stability as brand-name drugs."[2] Generic drugs today account for nearly 80% of prescriptions dispensed in the United States, but just 27% of prescription drug

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[1] The parties' letters of consent to the filing of *amicus* briefs have been filed with the Clerk. Under S. Ct. Rule 37.6. *amicus curiae* states that no counsel for a party wrote this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the *amicus curiae* or its counsel, has made a monetary contribution to this brief's preparation or submission.

[2] Generic Drugs: Questions and Answers. U.S. Food and Drug Administration, available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafe-ly/UnderstandingGenericDrugs/default.htm.

spending.[3] More than 3.2 billion prescriptions each year are filled with generic pharmaceutical products, saving the American consumer $193 billion in 2011 and more than $1 trillion over the last 10 years. ("GPhA Rpt.") GPhA's members are committed to providing safe, lower-cost medications to all Americans.

This case is one of many pending against GPhA members around the country despite this Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) *reh'g denied*, 132 S. Ct. 55 (2011). In *Mensing*, this Court recognized that under federal law generic pharmaceutical manufacturers are required to produce products that are the "same as" their brand-name counterparts. *Id.* at 2474-75. Because state tort-law requirements conflict with the federal duty of "sameness," this Court held those claims are necessarily preempted. *Id.* at 2570-71, 2474-75. Recognizing *Mensing's* broad preemption of claims, plaintiffs are attempting to end run that decision.

The First Circuit accommodated plaintiffs in their search for an alternative cause of action that might avoid preemption. Left standing, the First Circuit's decision defeats Congressional goals in enacting the Hatch-Waxman Amendments (the Drug

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[3] IMS Institute for Health Care Informatics, The Use of Medicines in the United States: Review of 2011, at 26 (Apr. 2012) ("IMS 2012"); Generic Pharmaceutical Association, Generic Drug Savings in the U.S. (4th ed. 2012), available at http://www.gphaonline.org/sites/default/files/IMS%20Study%C20Aug%C202012%20WEB.pdf ("GPhA Rpt.").

Price Competition and Patent Term Restoration Act of 1984, P.L. 98-417, 98 Stat. 1585 (1984)) and the Federal Food, Drug, and Cosmetic Act ("FDCA"), undermines this Court's holding in *Mensing*, and threatens the generic drug industry's ability to sell low-cost generic drugs.

INTRODUCTION

Lawsuits involving pharmaceutical products have increased exponentially over the past few decades. In contrast to the approximately 11,000 lawsuits (total) filed in federal courts against pharmaceutical companies during the 13-year period from 1973 through 1986,[4] today it is not uncommon for hundreds of lawsuits to be filed in a single day. Yet, while the sheer number of lawsuits involving pharmaceutical products has changed dramatically, what has not changed *one iota* is the nature of those claims. From the earliest case involving a medicinal, the claim has been premised on the product's labeling. *See Thomas v. Winchester*, 2 Seld. 397, 6 N.Y. 397 (N.Y. 1852), 1852 WL 4748 (N.Y.) (recognizing claim based on labeling of medicinal product). *See also Mazetti v. Armour & Co.*, 75 Wash. 622, 135 P. 633 (1913) (same); *Darks v. Scudders-Gale Grocer Co.*, 146 Mo. App. 246, 130 S.W. 430

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[4] The number of lawsuits ranged from fewer than 100 in 1974 to a high of around 1,600 in 1985. *See* Rand, Product Liability and the Business Sector. Litigation Trends in Federal Courts. 1988. Of those 11,000 lawsuits, almost 7,000 involved only two products (Dalkon Shields and Bendectin) and only two manufacturers (A.H. Robbins and Merrell Dow). *Id.* Litigation involving generic drugs was virtually unknown.

(1910) (same); *Blood Balm Co. v. Cooper*, 5 L.R.A. 612, 10 S.E. 118 (Ga. 1889) (same). That is so because even 100 years ago, it was recognized, *and accepted*, that medicinals generally have properties that can be dangerous or poisonous and, as a result, those products required adequate instructions for use – exactly what the FDCA requires today. *See, e.g.*, 21 U.S.C. 352(f) (declaring drug product misbranded where its labeling does not include "adequate directions for use").

As state product liability law developed over the years, the concept that pharmaceutical products are incapable of being made completely safe and without any risks became embedded in the law of virtually every state. The offshoot of that recognition was that pharmaceuticals that are properly prepared and accompanied with adequate directions for use are not considered defective – either in design or otherwise. *See, e.g.*, Restatement (Second) of Torts, §402(a) cmt. k (recognizing that products such as pharmaceuticals are unavoidably unsafe and not defective if properly prepared and accompanied by adequate instructions). With few exceptions not applicable to drugs with a single active ingredient (like sulindac), pharmaceutical litigation continued along that path until this Court decided *Mensing*. At that point, plaintiffs sought a cause of action they could argue did not depend on the generic drug labeling and, thus, would not be barred by the broad preemptive scope of *Mensing*.

Ms. Bartlett found herself in the same position, but for reasons unrelated to *Mensing*, which

had not been decided yet. While *Mensing* was winding its way through the courts, the district court dismissed Ms. Bartlett's failure-to-warn claim because she could not satisfy the most basic element of her claim – legal causation. As no one ever reviewed the product's labeling, Ms. Bartlett was unable to demonstrate that any inadequacy in the labeling was the proximate cause of her injury. The district court solved Ms. Bartlett's dilemma by allowing her to pursue a "defective design" claim – one that allegedly did not depend on the product's warnings. By the time Ms. Bartlett's case reached the Court of Appeals, *Mensing* had been decided, but the First Circuit chose not to apply it even though it recognized that Ms. Bartlett's claim depended on the adequacy of sulindac's labeling.

As this case clearly demonstrates, the nature of pharmaceutical products and their complex approval process have dictated that, with limited exceptions, lawsuits involving pharmaceutical products are failure-to-warn claims. Describing the claim as one for "design defect," as was done here, does not change the true nature of the claim and where those lawsuits target generic drugs, they are preempted by *Mensing*.

Yet, even if one accepts that a claim for design defect involving a generic drug does not involve the product labeling, the result is the same. Whether the basis of the claim is the generic drug's warnings or its design, the "sameness" requirement applies. Rationalizing the outcome based on the generic drug manufacturer's freedom to choose whether to sell its

product raises problems of its own, not the least of which is it subverts (indeed, inverts) the Supremacy Clause and prevents the successful application of the defense. In addition, that rationalization undermines both the Hatch-Waxman Amendments and the FDCA.

THE PROCEEDINGS BELOW

This lawsuit proceeded to trial as a purported strict liability design defect claim following the dismissal of Ms. Bartlett's other causes of action, including her failure-to-warn claim. Notably, Mutual was granted summary judgment on the failure-to-warn claim due to Ms. Bartlett's inability to establish that any alleged inadequacy in the warnings was the proximate cause of her injury because no one—not Ms. Bartlett and not her prescribing physician—ever read Mutual's sulindac package insert.

Ms. Bartlett's design defect claim suffered from a second factual roadblock: Sulindac is a molecule and, therefore, cannot be "defective" as that term is understood in state-law product liability actions; it can be only what it *is* and *cannot* be designed any differently. To solve those problems, the district court declared proximate cause "was out of the case"[5] (CA Add. 44; CA Appx. 1281-83, 1285), and (contrary to longstanding precedent[6]) eliminated

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[5] Ms. Bartlett's only burden on causation was to establish medical causation (cause-in-fact).

[6] *Compare* JA 279-80 (holding Ms. Bartlett "can prevail on a products liability claim by proving that a product was

the "defect" requirement from the claim entirely, declaring that Ms. Bartlett could succeed on her "defective design" claim merely by establishing sulindac was unreasonably dangerous.[7]

However, even under the district court's "defective design" theory, the determination of unreasonable danger necessarily turned on the adequacy of the product's warnings. The jury instructions tell the tale:

> Now, if you determine that sulindac was unreasonably dangerous, you may consider the presence and efficacy or effectiveness of a warning to avoid an unreasonable risk of danger from foreseeable uses of the product. The plaintiff must prove that the product was unreasonably dangerous even with its warning.

'unreasonably dangerous pursuant to the risk-utility balancing test'....") *with Buckingham v. R.J. Reynolds Tobacco Co.*, 142 N.H. 822, 713 A.2d 381 (1998) (holding plaintiff must allege and prove that (1) a defect existed in the product and (2) because of the defect the product was unreasonably dangerous. New Hampshire law is addressed merely to emphasize the stark contrast between the unique claim sanctioned here that required no evidence of a defect and the historically-recognized failure-to-warn claim applicable to most prescription pharmaceuticals.

[7]Under the district court's creation, "defective condition" and "unreasonably dangerous" became synonymous even though the jury was asked to decide if the "defective condition" made sulindac "unreasonably dangerous." (JA 519, 512.)

> If you determine that sulindac was unreasonably dangerous and that a warning was not present and effective to avoid that unreasonable danger, then you must find Mrs. Bartlett has proven this element of her claim, a defect in design. However, if you determine that sulindac was unreasonably dangerous, but that a warning was present and effective to avoid that unreasonable danger, then you must find for Mutual.

(JA 513-14.) The jury, however, was not told that Mutual, as a generic drug manufacturer, could not change the sulindac labeling.[8] Furthermore, the jury was told to evaluate warnings as part of the risk/benefit analysis,[9] but was not told that Ms. Bartlett and her prescribing physician never saw Mutual's sulindac labeling. (*Id.*) In short, the district court permitted Ms. Bartlett to present a failure-to-warn claim to the jury, but without the burden of proving proximate cause.

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[8] The district court had denied Mutual's motion based on federal preemption twice before trial holding both times – incorrectly pursuant to *Mensing* – that Mutual was not precluded by federal law from changing the sulindac package insert. (PA 142a-202a; 140a.)

[9] The district court also instructed the jury that in considering the "presence and efficacy of a warning to avoid an unreasonable risk of danger" it could "consider the FDA's requirements for drug labels." (JA 516.) The court then read FDA's regulations relating to the format and content of prescription drug labeling to the jury. (JA 516-518.)

The First Circuit acknowledged that the risk/benefit evaluation at the heart of Ms. Bartlett's "design defect" claim depended on the adequacy of the sulindac labeling, (PA 18a-19a ("[T]he label was relevant to the design defect claim since, although unalterable by Mutual, its arguable inadequacies put limits on the extent to which its dangerousness was offset by adequate warnings; so the lack of clearer warning made the product itself more dangerous under the risk-benefit test...."), and recognized sulindac's design could not be changed (PA 10a ("Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)....")). Nonetheless, the First Circuit accepted the fiction that the labeling could be alternately separated from (to state the claim) and joined to (to assess the claim) the sulindac tablet as plaintiff's needs suited and ruled that *Mensing* did not preempt "design defect" claims. Rather than faithfully apply *Mensing* to the *real* claim in this case, the First Circuit relied on the "logic" of this Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), to conclude that the "FDCA might permit states to tell Mutual it ought not be [making or marketing its product]." (PA 10a-11a.)

SUMMARY OF ARGUMENT

The First Circuit's decision stands in stark contrast to and cannot be reconciled with the federal law governing generic drug products or this Court's decisions. The Drug Price Competition and Patent Term Restoration Act governs the approval and sale of generic drugs in the United States. Under 21

U.S.C. §355(j), a generic drug must be the same as the reference listed drug ("RLD") upon which it is based. That sameness requirement applies to the "active ingredient," the "dosage form and strength," "the route of administration," and "labeling." *See* 21 U.S.C. §355(j). In *Mensing*, this Court recognized the "federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers," and that "different federal statutes and regulations may, as here, lead to different pre-emption results." *Mensing* 131 S. Ct. at 3582. It held that the plaintiffs' lawsuits aiming state-law claims against generic drug manufacturers that conflict with those federal requirements are preempted.

To avoid the straightforward application of this Court's decision in *Mensing*, the First Circuit accepted the fiction that sulindac could be divorced from its labeling even while the jury was instructed that liability depended on the adequacy of the sulindac labeling. That the labeling was the pivotal issue of this lawsuit is not surprising. The reason is fairly evident when one considers the nature of pharmaceutical products and the long history of tort law that has developed as a result. To be more precise, a drug without its labeling has no identified benefits and no identified risks. It, therefore, is impossible to either state a claim or prove a claim that a drug product's risks outweigh its benefits (i.e., is "defective in design") without reference to and evaluation of the product's label, which leads to the conclusion that where drugs are concerned, the product liability claim is one for "failure to warn." In

the context of lawsuits against generic drug manufacturers, that means the claim is preempted.

Although recognizing that Ms. Bartlett's "design defect" claim depended on sulindac's warnings, the First Circuit tried to side-step *Mensing* by describing it as an "exception" to *Levine's* "general no-preemption rule." (PA 9a, 11a.) The First Circuit then proceeded to apply that "general no-preemption rule" to Ms. Bartlett's "design defect" claim to uphold the verdict. The First Circuit simply chose not to apply *Mensing* without any discussion of the relevant statute, even though *Mensing's* rationale applies equally to the design and labeling of generic drugs, and instead applied the "logic" of *Levine*, even though this Court acknowledged in *Mensing* that *Levine* did not apply to generic drugs. *Mensing*, 131 S. Ct. at 2581-82.

The First Circuit's ultimate rationale for concluding that Ms. Bartlett's claim was not preempted; i.e., that Mutual did not have to sell its product, sidesteps the preemption analysis. There cannot be a conflict between federal law and state law if no law applies. Under the First Circuit's rationale, the preemption issue never arises. That analysis is no analysis at all. Moreover, if, as the First Circuit held, a state might be permitted to tell a manufacturer it ought not sell its federally-approved product, either directly or by imposing damages, state law effectively would preempt federal law.

The First Circuit's rationale carried to its conclusion would thwart Congress's objectives in

enacting not only the Hatch-Waxman Amendments but also the FDCA. While Congress intended to increase the availability of low-cost generic drugs, the First Circuit's suggestion that a state might, through a jury, prohibit the sale of generic drugs or assess damages based on the sale of the federally-approved product would have the effect of decreasing the availability of low-cost generic drugs, either because those drugs are no longer sold, or because they are available only at significantly increased prices.

The First Circuit's decision also threatens the drug approval process – one that has been in place for many decades. Years ago, Congress decided to centralize approval decisions relating to drug products in FDA. The First Circuit advocates that lay jurors who likely will have little to no relevant education or experience should be permitted to second-guess FDA's analysis and make the complex scientific decisions involved in assessing the risks and benefits of drug products and whether they should be sold in interstate commerce. It ignores the disparity of information a jury will have available to it to make that decision from the information available to FDA and offers no justification for wresting that decision from the agency Congress, decades ago, vested with responsibility for making it.

The First Circuit would leave manufacturers to the whims of state-law juries, who will be asked to, and will decide, based on limited cherry-picked information, whether a drug product's risks outweigh its benefits. It takes years for FDA to assess a drug's

safety profile. In contrast, a jury trial involving pharmaceutical products is measured in days or weeks, during which time not only is testimony related to the actual drug presented, but also testimony related to the plaintiff's injury, life, and medical history. In sum, two or three days, maybe less or maybe a little more, of that trial *may* be devoted to testimony regarding the drug and its alleged benefits and risks.[10] The First Circuit would have a jury, who receives two to three days of information in the context of hearing only a single plaintiff's tale, second-guess a decision an expert agency developed over several years. That result flies in the face of the FDCA.

Without the ability to change the design of the drug or to change the drug's labeling, the First Circuit's decision subjects generic drug manufacturers to absolute liability if they choose to sell generic drugs. The First Circuit's alternative, withdrawing from the market to avoid damages, would inevitably result in the unavailability of low-cost generic drugs to the detriment of the American public.

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[10] The trial in this case lasted slightly less than three weeks, and a significant amount of that time was spent on issues outside the presence of the jury. (*See generally* District Court's Transcript of Proceedings.)

ARGUMENT

A. "Design Defect" Claims Are Directed To the Product's Warnings

Last term, this Court explained that the design of a product and its warnings are connubial concepts. In rejecting the plaintiffs' contention in *Kurns* that "[t]he basis of liability for failure to warn ... is not the 'design' or 'manufacture' of a product," but rather "the failure to provide adequate warnings regarding the product's risks," this Court recognized that

> [a] failure-to-warn claim imposes liability on a particular design of [a product] unless warnings deemed sufficient under state law are given. This duty to warn and the accompanying threat of liability will inevitably influence a manufacturer's choice whether to use that particular design. By influencing design decisions in that manner, failure-to-warn liability has a "'direct and substantial effect' on the "physical elements" of a [product].

Kurns v. Railroad Friction Products Corp., 132 S. Ct. 1261 (2012).

The relationship between a product's design and its labeling is particularly germane to pharmaceuticals. A drug's initial risk profile is developed during clinical trials conducted to support

approval of the new drug application ("NDA"), and the risk profile is defined in the product's labeling. Unlike many products, a drug's risks cannot be altered or improved by changing the design, i.e., its active pharmaceutical ingredient ("API")[11], for the simple reason that a drug with a different API is a different drug – one that has its own risk profile. *See, e.g., Sprague v. Upjohn Co.*, No. 91-40035, 1995 WL 376 934, at *1 (D. Mass. May 10, 1994) ("Halcion is incapable of being ... redesigned. To alter the chemistry of the [t]riazolam molecule, would be to create a new ... product."). Therefore, with respect to pharmaceutical products, the "physical element"[12] (the API) necessarily defines the warnings. Indeed, the warnings for a pharmaceutical product are drafted for a product with a specific API – and none other. As a result, claims involving a pharmaceutical product necessarily arise from the product's labeling; they allege either that the pharmaceutical product labeling failed to adequately disclose the risks inherent in the product when the NDA was approved or failed to account for new data after approval.

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[11]References to the "design" of a drug are to API because it is the relevant constituent of a drug that is the subject of state-law claims. While inactive ingredients can be changed, they seldom are the subject of personal injury lawsuits, and were not the subject of this lawsuit.

[12]Generic drug manufacturers have no "choice" in the "particular design" of their products. The "design" is limited to the approved API for the reference listed drug.

Attempts to selectively untether the design of a prescription drug from its labeling by allowing a claim that "the drug's risks outweighed its benefits" making it unreasonably dangerous ignore one very salient fact: The FDA-approved "benefit" is derived only by reference to the approved indications in the product labeling, and the source of the "risks" to which the benefits are compared also is the FDA-approved labeling. In other words, a pharmaceutical product cannot be divorced from its label as it is not possible to conduct a risk/benefit (i.e., design defect) evaluation without the product labeling.

The concept that a drug is nothing without its label is both a practical and a legal concept. Imagine being handed a small round pill. One cannot hold that pill in the palm of one's hand and know its active ingredient, what benefit it might deliver, and what risks it may present. The pill is given meaning only by the label that identifies that ingredient. However, knowledge of the ingredient itself is not sufficient to give the product utility. One must know the product's uses, the dose at which it should be administered, its contraindications, the risks associated with its administration, as well as the other information in the labeling.[13] None of that is evident without the labeling. In fact, drug products are approved for sale by the FDA as safe and effective for use as recommended in the submitted labeling. (*See, e.g.*, CA 2169 (Defendant's Ex. 188, Letter from R. Williams to Mutual, April 17, 1991

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[13] It is exactly for that reason that Congress entered the field of drug regulation over a century ago.

(approving Mutual's sulindac as "safe and effective for use"); *see also* 21 U.S.C. §355(d) (requiring FDA to refuse approval of new drug application where application does not include data to show drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling").) In that regard, drugs are unique. One can look at a ladder and surmise its purpose and its benefits – to help humans reach higher places than they could without it; one cannot look at that small round pill and know its purpose or its benefits. Reference to the approved labeling is required as the use of the product is a function of its approved labeling. As a result, it is impossible to allege the risks of a pharmaceutical product outweigh its benefits without implicating the labeling. Ms. Bartlett's allegation is a case in point.

Ms. Bartlett's design defect claim was that "sulindac was in a defective condition unreasonably dangerous to the user/consumer ... in that its foreseeable risks exceeded the benefits." (JA 104-105, ¶¶53, 55.) Sulindac's benefits (its approved uses as indicated on the product labeling) are that it treats osteoarthritis, rheumatoid arthritis, acute gouty arthritis, ankylosing spondylitis, and acute painful shoulder (acute subacromial bursitis/supraspinatus tendinitis).[14] (JA 553.) The foreseeable risk Ms. Bartlett targeted was an alleged

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[14] Sulindac is the only NSAID approved to treat acute painful shoulder (acute subacromial bursitis/supraspinatus tendinitis) (the condition for which it was prescribed to Ms. Bartlett (JA 82, ¶8)) and acute gouty arthritis. (PA 46a.)

potential to cause rare, idiosyncratic allergic reactions – Stevens Johnson Syndrome ("SJS") and toxic epidermal necrolysis ("TEN") – both identified in the sulindac labeling. (JA 554.) In other words, she claimed that sulindac did not have the efficacy disclosed in the package insert, or that it presented risks greater than those set forth in the package insert. Plaintiffs' allegations make that much clear. That is why the First Circuit ultimately acknowledged that the product's warnings are an integral part of the analysis. (PA 18a-19a.)

There can be no doubt that design defect claims involving a pharmaceutical product directly target the product warnings and in substance are failure-to-warn claims. That conclusion is inescapable given that part and parcel of the drug's approval is the approval of the drug's labeling. One is not, and cannot, be approved without the other. *See* 21 U.S.C. §355.

That is not to say that drug product labeling is static; it is not. The risk profile of a drug continues to develop over the course of the years it is marketed. When, and if, new risks are identified, either the brand-name drug manufacturer or FDA will institute a label change to reflect the changed risk profile. Generic drug manufacturers then will follow suit, changing their labels to be the same as the reference listed drug. Those facts do not detract from the maxim that a drug and its label must be evaluated together. Rather, they reinforce that the underlying premise of the claim against a drug manufacturer remains a failure-to-warn claim. Under this Court's

decision in *Levine* and *Mensing*, a brand-name manufacturer may be subjected to state-law liability for a failure to warn, but a generic drug manufacturer may not.

B. THE FIRST CIRCUIT'S DECISION IS IN DIRECT CONFLICT WITH BOTH THE HOLDING AND RATIONALE OF *MENSING*

Recognizing the inseparability of the label from the evaluation of a drug's design, it is clear Ms. Bartlett's claim was merely a disguised failure-to-warn claim. The First Circuit decision not to apply *Mensing* directly conflicts with both the holding and the rationale of *Mensing*.

The First Circuit understood that Ms. Bartlett's claim depended on sulindac's warnings: "[T]he label was relevant to the design defect claim since, although unalterable by Mutual, its arguable inadequacies put limits on the extent to which its dangerousness was offset by adequate warnings; so the lack of clearer warning made the product itself more dangerous under the risk-benefit test...." (PA 18a-19a.) In other words, the First Circuit recognized that the *only* change that could be made to alter sulindac's risk/benefit equation was a change to the labeling. That recognition should have ended the analysis because it identified that the true nature of the claim before it was based on the product's warnings and *Mensing* bars that claim. The First Circuit, however, discounted the significance of the labeling by asserting that the claim was not a failure-to-warn claim, as though

Mensing did not apply if the failure-to-warn claim simply was given a different name.

Ignoring the fact that "federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers," and that "different federal statutes and regulations may ... lead to different pre-emption results," *Mensing*, 131 S. Ct. at 2582, the First Circuit chose to apply the "logic" of *Levine* rather than the "logic" of *Mensing*. According to the First Circuit, this Court adopted a "general no-preemption rule" in *Levine* to which *Mensing* was merely an exception that applied to claims premised on inadequate warnings involving generic drugs. (PA 8a-11a.) The First Circuit recognized that *Levine* involved brand-name drugs and that its "holding was technically limited to failure-to-warn claims," but nonetheless concluded that *Levine's* "logic applies to design defect claims" involving both brand-name and generic drugs. (*Id.* 9a and n.2.) Yet, it chose not to apply the "logic" in *Mensing* because *Mensing* merely "carved out an exception to *Wyeth*, finding that the FDCA preempts failure-to-warn claims against generic drug manufacturers" (*id.*), and that the question of whether the FDCA similarly preempts "design defect claims against generic drug manufacturers ... has yet to [be] decide[d]." (*Id.* 8a.)

However, even if the design defect claim did not depend on the product labeling, the "same as" requirement in 21 U.S.C. §355(j), applies to much more than labeling—it applies to the generic drug's

design; i.e., its "active ingredient," "route of administration," "dosage form," and "strength." The First Circuit never referenced the statute and offered absolutely no explanation of why the analysis should differ for a design defect claim.

C. Removing the Product From the Market Does Not Resolve the Conflict and Raises Conflicts of Its Own

Acknowledging, as they must, that Mutual could not change the sulindac molecule (either physically or legally), the district court, and ultimately the First Circuit, concluded that the claim was not preempted because Mutual could have chosen not to sell its product. (PA 10a, 11a.) Fundamentally, that solution ignores necessary elements of the preemption analysis and elevates state law over federal law. Moreover, it is irreconcilable with Congress's purposes and objectives in enacting Hatch-Waxman as well as Congress's purposes and objectives in enacting the FDCA.

1. The First Circuit's Decision Ignores Necessary Elements of the Preemption Analysis and Elevates State Law over Federal Law

"The Supremacy Clause establishes that federal law 'shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Mensing*, 131 S. Ct. at 2577 (quoting U.S. Const. Art. VI, cl. 2.) The First

Circuit decided Ms. Bartlett's state-law claim is not preempted because Mutual could avoid state law damage awards by merely choosing not to sell its federally-approved product. (PA 10a, 11a.)

The First Circuit's analysis and decision ignores a basic, fundamental premise: If the product is not on the market there are no applicable laws. With respect to the sale of products that are federally regulated that means there is no applicable federal law and, concomitantly, there is no applicable state law. It is not until the manufacturer sells a product that the laws and the Supremacy Clause become applicable.

In the case of generic drugs that means the manufacturer must comply with the requirements in 21 U.S.C. §355(j). On the state level, the manufacturer must ensure its product is safe and adequately labeled. As a result, the preemption analysis requires: (1) the product to be on the market; (2) an applicable federal law – here the Hatch-Waxman Amendments to the FDCA and FDA's regulations governing generic drugs; and (3) an applicable state law – here state product liability law.

If those facts do not exist, there is no federal law that can be supreme to the law of any state. If Mutual had not sold sulindac, there would be no lawsuit and this case would not be before this Court. The Supremacy Clause anticipates – in fact, requires – an applicable federal law and an applicable state law. The First Circuit's rationale

would simply eliminate the need to apply the Supremacy Clause—a result this Court rejected. *See Mensing*, 131 S. Ct. at 2579 ("We do not read the *Supremacy* Clause to permit an approach to preemption that renders conflict pre-emption all but meaningless.").

Moreover, the First Circuit's conclusion that it was appropriate to assess damages against Mutual because it chose to sell its federally-approved product – a product whose design and labeling it could not change – elevates state law over federal law. Rather than avoiding the conflict, the First Circuit's solution heightens it.

2. The First Circuit's Decision Conflicts with Congress's Purposes and Objectives in Enacting Hatch-Waxman

In 1984, in recognition of the need for a less-costly procedure for approval of generic drugs, Congress passed the Hatch-Waxman Amendments. The overriding purpose of the Amendments was to increase the availability of low cost generic drugs. *See* "P.L. 98-417, Drug Price Competition and Patent Term Restoration Act," H.R. Rep. No. 857(I), 98th Cong., 2d Sess. (1984), reprinted in 1984 U.S.C.C.A.N. 2647; *New Drug Application: Hearings on H.R. 3605 Before the Subcomm. On Health and the Environment of the House Comm. on Energy and Commerce*, 98th Cong., 1st Sess. (1983); Drug Price Competition and Patent Term Restoration Act of 1984, Committee Notes, 130 Cong. Rec. 24416, H.R.

3605 (daily ed. Sept. 6, 1984); Drug Price Competition and Patent Term Restoration Act, Committee Notes, 130 Cong. Rec. 24970, S. 1538 (daily ed. Sept. 12, 1984). One would be hard-pressed to conjure a more frontal attack on Congressional objectives than the suggestion that generic drug companies avoid state-law liability by either withdrawing their products or not selling them in the first instance.[15] While Congress intended to promote and make low-cost generic drugs more readily available, the First Circuit advocates generic drug companies unilaterally withdraw those same drugs from the market thereby decreasing their availability.

The alternative of simply paying damages for selling the generic drug is no better. The First Circuit would have juries assess large and repeated damages against generic drug companies for selling the drugs Congress sought to have approved and sold. The higher prices that would result again subvert Congressional objectives.

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[15] Likewise, it would be contrary to the purposes of the expedited approval process applicable to generic drugs to place companies in the untenable position of extensively researching marketed pharmaceuticals to second guess the FDA's conclusions whether they are safe and effective before making generic versions of those drugs.

3. Permitting Juries to Second-Guess FDA's Risk-Benefit Determinations Conflicts with Congress's Purposes and Objectives in Enacting the FDCA

In 1938, Congress revamped the Pure Drug and Food Act passed in 1906, and vested authority in a federal agency to review and approve drug products before they could be sold in the United States. The passage of the FDCA marks the advent of the requirement that drugs be approved before they can be sold. The 1938 Act placed exclusive authority in FDA to determine whether a drug product was safe for sale in interstate commerce. That exclusive authority remains in FDA today.

However, in the wake of *Mensing*, plaintiffs are inviting and encouraging courts to wrest that authority from FDA's hands and place it in the hands of juries across the country – an invitation the First Circuit accepted. Rather than having the agency designated by Congress, which is staffed with highly trained physicians and scientists who have access to neutral outside expert advisory committees determine whether drugs may be sold, the First Circuit advocates placing that function in the hands of jurors with access only to incomplete, biased information. Instead of having the agency that possesses all the information regarding a drug – the original clinical studies, all adverse events reported since the initial sale of the drug (from all sources), the worldwide medical literature, and all the data regarding other marketed drugs – decide its safety

for sale, the First Circuit favors placing that determination in a jury's hands.

Yet, a jury is provided only that small subset of data that counsel chooses to present through experts it chooses. The data will be limited to that which focuses on the injury or risk at issue in the lawsuit. The expert will be biased. An untrained jury of the plaintiffs' peers will be asked to decide whether the limited information they are given warrants the withdrawal of the drug product from that state's market – for all people and for all purposes. Ultimately one state-law jury's determination effectively could result in withdrawal of the drug product throughout the country, placing inappropriate and unauthorized burdens on interstate commerce.

This Court recognized that potential in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008), when it observed that juries are ill-equipped to regulate medical products.

> A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by the [drug] which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients

> who reaped those benefits are not represented in court.

The Eighth Circuit Court of Appeals made a similar observation in *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 797 (8th Cir. 2001): "It would be difficult for a jury focused on a single case to take into account 'the cumulative, systemic effects' of a series of verdicts. In contrast, the FDA possesses a broader perspective." That is why courts, including this one, have rejected attempts by plaintiffs to usurp FDA's powers and authority. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348-53 (2001) (finding tort claim prohibited because it conflicts with FDA's authority to police fraud according to its own "delicate balance of statutory objectives"); *Robinson v. McNeil Consumer Healthcare*, 2010 WL 3156548 (7th Cir. Aug. 11, 2010) (holding claims for selling over-the-counter drug without stronger warnings of prescription version prohibited because "[t]he decision whether to permit a drug to be sold over the counter rather than just be prescription is for the FDA.... The agency bases its decision on whether the drug is safe and effective for use without a doctor's permission ... and it has decided not to require [the drug] be sold by prescription only"); *Autin v. Solvay Pharms., Inc.*, 2006 U.S. Dist. LEXIS 19507 (W.D. Tenn. Mar. 31, 2006) (concluding "court cannot usurp FDA's power to evaluate the effectiveness of a drug or to approve a drug").

The verdict in this case bears out those concerns. Even though the potential risk of developing SJS/TEN (an idiosyncratic, allergic

reaction that cannot be predicted), according to Ms. Bartlett's experts, occurs only in between one to two patients per million (JA 424), a lay jury of ten members, presented with limited information (far less than FDA possesses), determined that sulindac should not be marketed at all. In other words, they decided based on their purported risk/benefit analysis that the risk to those few exceeded the benefits for the 999,998 patients per million who used the drug beneficially. And, they reached that conclusion despite the fact that FDA concluded after extensive analysis that sulindac should not be withdrawn from the market.

In enacting the FDCA, Congress established a uniform, feasible, safe, and economically sound set of rules implemented by experts at a single agency to determine drug safety and approve drugs for sale. Approval of drugs for sale belongs in FDA's hands and not a jury's.

Indeed, the First Circuit recognized that permitting juries to evaluate whether the risks of a drug product outweighed its benefits and whether a drug should be sold amounted to "second-guessing the FDA," but concluded that "*Wyeth* resolved the conflict against general preemption." (PA 10a.) While FDA approval alone has never found favor as a grounds for preempting state-law claims, it is an unwarranted extension of *Levine* to sanction the substitution of a jury's risk/benefit analysis for that of FDA, especially in the circumstance where a generic pharmaceutical company has no choice in either the risks or benefits it discloses and where the

only alternative is removal of the product from the market in direct contrast to the statute's core objectives. Indeed, for the branded drug company, the conclusion that a product's labeling does not accurately describe the drug's potential risks is remedied through a revised package insert, rather than through the draconian conclusion that the product should not be sold.

It also raises the specter of why Congress enacted the FDCA and centralized the safety and efficacy determination regarding drugs and whether or not they should be sold in interstate commerce in FDA. Had Congress intended lay juries to make that decision, it simply could have left matters as they stood. The complexity of drug products, however, counseled the development of a single agency staffed with professionals who have both the training and experience to make informed decisions. Those decisions should not be placed in the hands of juries.

D. Left Standing, the First Circuit's Decision Would Severely Impact the Generic Drug Industry and the Availability of Generic Drugs

The savings to American consumers and federal and state governments since the Hatch Waxman Amendments were enacted are not subject to debate. (*See* GPhA Rpt. (noting sale of generic drugs has saved American consumers more than $1 trillion over the last 10 years.) Generic drugs do not pose additional risk to patients because FDA already

has determined that the drug is safe and effective when accompanied by the FDA-approved labeling.

The landscape will change dramatically if the First Circuit's "defective design" type claim is allowed. No longer will generic drug manufacturers and the public be able to rely on FDA's safety and efficacy determination. No longer will they be able to rely on the sufficiency of the package insert. Instead, generic drug manufacturers will be faced with the prospect of absolute liability for every drug they sell – drugs for which they cannot change the warnings or other aspects of the design. The unprecedented imposition of absolute liability will force them (and others who may bear the risk such as insurance companies) to reassess the wisdom of being a market participant.[16]

The American public will feel the impact as generic drug prices inevitably will rise. The strides that have been achieved since the Hatch-Waxman Amendments were enacted will be lost. While today nearly 80% of all prescriptions are filled with generic drugs at only 27% of prescription drug costs (*see* IMS 2012), tomorrow's tale could be far different.

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[16] The First Circuit's decision makes the environment even more hostile for generic drug manufacturers by removing causation from the elements a plaintiff is required to prove in order to prevail on a "design defect" claim. It affirmed the district court's decision that a "design defect" claim could be submitted to the jury based on alleged deficiencies in Mutual's labeling even though neither Ms. Bartlett nor her prescribing physician ever saw Mutual's labeling.

In short, the First Circuit's "defective design" claim threatens to turn back the clock, decrease competition, and increase prescription drug costs.

CONCLUSION

The First Circuit's decision should be reversed.

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AMICUS CURIAE BRIEF

FOR
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BRIEFS

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IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF JOHN AND TAMMY GILBERT, DEBORAH KINTER, DONALD BROWN, AND ALICE SZROMBA, ON BEHALF OF PERSONS INJURED BY PROPOXYPHENE, AS AMICI CURIAE IN SUPPORT OF RESPONDENT

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INTEREST OF THE AMICI CURIAE[1]

Amici John and Tammy Gilbert, Deborah Kinter, Donald Brown, and Alice Szromba submit this brief on behalf of persons injured by the prescription drug propoxyphene (sold both as a generic drug and under the brand names Darvon and Darvocet). Propoxyphene is a paradigm example of an unreasonably dangerous prescription drug that should never have been sold. Thousands of persons suffered serious cardiac injuries or death as a result of their use of propoxyphene before November 2010, when the federal Food and Drug Administration ("FDA") finally concluded that the drug's serious risks outweighed its questionable therapeutic benefits and asked all manufacturers of propoxyphene to withdraw the drug from the United States market. *Amici* Gilbert, Kinter, Brown, and Szromba are all plaintiffs in pending product liability lawsuits against manufacturers of propoxyphene in which plaintiffs have asserted, *inter alia*, causes of action for strict liability design defect and/or closely related causes of action under state law. Their claims may be directly affected by the Court's ruling in this case.

John and Tammy Gilbert's only child, Kira, a healthy 22-year old, died suddenly of a heart attack after ingesting generic propoxyphene, prescribed to

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[1] No counsel for a party authored this brief in whole or in part, and no party or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than *amici curiae* or their counsel made any monetary contribution to this brief's preparation or submission. The parties' letters of blanket consent to the filing of amicus briefs have been filed with the Clerk.

her for pain relief. Their lawsuit against the propoxyphene manufacturer, transferred to the Darvon, Darvocet, and Propoxyphene Multidistrict Litigation ("MDL") proceeding before the U.S. District Court for the Eastern District of Kentucky, was dismissed on grounds of preemption and is now on appeal to the United States Court of Appeals for the Sixth Circuit. Deborah Kinter's brother, Blaine, died at age 58 from cardiac dysrhythmia (an abnormal heartbeat) as a result of his use of generic propoxyphene. Her claims against the manufacturers were also dismissed by the MDL district court and are now pending before the Sixth Circuit. Donald Brown experienced chest pains, angina, fatigue, and heart arrhythmias as a result of his use of both brand-name and generic propoxyphene. He eventually developed supraventricular tachycardia ("SVT"), which necessitated an SVT ablation and the implantation of a heart pacemaker. Mr. Brown's claims against the manufacturers of generic propoxyphene were dismissed by the MDL court, but his claims against the manufacturers of Darvon remain pending. Alice Szromba, the mother of two young children, suffered atrial fibrillation and other heart injuries, necessitating ablation surgery, as a result of a single ingestion of a generic propoxyphene product. Her lawsuit against the propoxyphene manufacturer was filed in Imperial County Superior Court in California, subsequently removed to federal court, and at present awaits a ruling on a pending motion to remand.

Darvon was first approved by the FDA in 1957 for the treatment of mild to moderate pain. At the time, federal law did not require drug manufacturers to prove that a drug was safe and effective in order to obtain FDA approval; instead, the FDA was required

to approve an application to market a new prescription drug unless it could establish that the drug was unsafe. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). In 1972, the FDA approved Darvocet, a product combining propoxyphene with acetaminophen. Following the passage of the federal Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Amendments") in 1984, Pub. L. No. 98-417, 98 Stat. 1585, numerous generic drug companies obtained approval to market generic versions of both Darvon and Darvocet.

Concerns about propoxyphene's risks arose many years ago. The first Citizen Petition asking for propoxyphene to be banned as an "imminent hazard" was submitted to the U.S. Department of Health, Education and Welfare in 1978. Public Citizen, *Petition to Ban All Propoxyphene (Darvon) Products* (Feb. 28, 2006), *available at* http://www.citizen.org/Page.aspx?pid=697.

In 2005, the British government began a phased withdrawal of propoxyphene products, on the grounds that the drug's efficacy in treating pain was poorly established and the risk of toxic reactions was unacceptable. *Id.* The British government statement concluded: "It has not been possible to identify any patient group in whom the risk-benefit [ratio] may be positive." *Id.* In 2009, the European Medicines Agency recommended that member countries begin a phased withdrawal of propoxyphene products. *See* Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research to Public Citizen (July 6, 2009), at 6 (on file with author). The same year, an FDA Advisory Committee recommended that propoxyphene be withdrawn from the market. *Id.*

Finally, in November 2010, when the FDA determined that even approved therapeutic doses of propoxyphene put patients at risk of potentially serious or even fatal heart rhythm abnormalities, the FDA asked all manufacturers of propoxyphene products to withdraw their products from the market. *See* FDA, *FDA Drug Safety Communication: FDA Recommends Against the Continued Use of Propoxyphene* (Nov. 19, 2010), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm234338.htm. The FDA request was based on the FDA's conclusion that "the safety risks of propoxyphene outweigh its benefits for pain relief at recommended doses." *Id.*

In response to the FDA's request, manufacturers of propoxyphene voluntarily stopped selling their products. But this action came too late to prevent injury to the *amici* or their decedents.

INTRODUCTION AND SUMMARY OF ARGUMENT

FDA approval of a drug does not give its manufacturer "the unfettered right, for all time, to market its drug." *Wyeth v. Levine*, 555 U.S. 555, 592 (2009) (Thomas, J., concurring in the judgment). "It does not represent a finding that the drug . . . can never be deemed unsafe by later federal action, or as in this case, the application of state law." *Id.* Design-defect liability—and related common law bases for liability, such as negligent design, negligent marketing, and breach of the implied warranty of merchantability—provide important protection for persons injured by unreasonably dangerous products "that complements FDA regulation." *Id.* at 579 (majority opinion).

Design-defect claims are fundamentally different from failure-to-warn claims, such as the claims at issue in *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). A defectively-designed product is one that has been manufactured in accordance with its intended design, but that design poses unreasonable risks to users of the product. Such a product is "unreasonably dangerous" when the risks of the product exceed its benefits.

The absence of an adequate warning is not an element of a strict liability design-defect cause of action. Indeed, a defendant may be held strictly liable even where an adequate warning has been provided: warnings are not a substitute for supplying a reasonably safe product. The district court properly applied these principles in this case.

State-law design-defect claims are entirely consistent with and complementary to the FDA's regulatory system. Like the claims at issue in *Levine*, design-defect claims not only provide critically important compensation to persons injured by unreasonably dangerous drugs, they also provide incentives for manufacturers to respond promptly to emerging safety risks with their products and supplement the FDA's limited resources for monitoring the safety of drugs after they have been approved. Importantly, the test for imposing design-defect liability is the same as that employed by the FDA to determine whether a drug is unsafe for use: both ask whether a drug's risk of harm outweighs its therapeutic benefits.

Nor does state-law design-defect liability conflict with Congress's purposes in enacting the Hatch-Waxman Amendments. Although Congress

undoubtedly wanted to encourage the availability of less expensive generic versions of safe and effective prescription drugs, it certainly did not intend to ensure the sale of unreasonably dangerous drugs, whether branded or generic.

Petitioner can "independently do under federal law what state law requires of it." *Mensing*, 131 S. Ct. at 2579. Nothing in federal law prohibits Petitioner from compensating Ms. Bartlett for her injuries caused by Petitioner's drug. Indeed, federal law does not even require drug manufacturers to sell their products. Petitioner was free to voluntarily withdraw its generic sulindac from the market at any time. That option enabled Petitioner to avoid any risk of liability for selling an unreasonably dangerous drug.

ARGUMENT

I. DEFECTIVE-DESIGN CLAIMS ARE FUNDAMENTALLY DIFFERENT FROM FAILURE-TO-WARN CLAIMS.

Petitioner Mutual Pharmaceutical Company, Inc. (hereinafter "Mutual") bases much of its argument for extending this Court's preemption ruling in *Mensing* on a startling proposition: "that failure-to-warn claims are in fact design-defect claims." Pet'r's Br. 34 (citing *Kurns v. R.R. Friction Prods. Corp.*, 132 S. Ct. 1261, 1268 & n.4 (2012) for this proposition); *see also id.* ("At least in the prescription-drug context, *design-defect claims are failure-to-warn claims*.") (emphasis in original). *Kurns* does not support Mutual's argument. And, as even a cursory examination of product liability precedent, treatises, restatements, or academic

literature makes clear, the proposition is false. Design-defect and failure-to-warn claims are analytically distinct causes of action, two of the three legs of the product liability triad (along with manufacturing defect claims). Unlike the warning claims at issue in *Mensing*, the absence of an adequate warning is not an element of a cause of action for defective design. While the presence of an effective warning can ameliorate—and, in some cases, perhaps even overcome—the risks of an unreasonably dangerous design, the absence of such a warning does not give rise to design-defect liability. The District Court here carefully considered and applied the distinctions between warning and design claims in its management of the litigation in this case.

A. The Absence of an Adequate Warning Is Not a Necessary Element of Design-Defect Liability.

As the *Restatement (Third) of Torts: Products Liability* succinctly observes:

> Abundant authority recognizes the division of product defects into manufacturing defects, design defects, and defects based on inadequate instructions or warnings. . . . Support among the treatise writers for a functional definition of defect, differentiating among manufacturing, design, and failure to warn defects, is equally strong. . . . Law review commentary similarly recognizes the distinction as necessary to a coherent discussion of the bases of liability.

Restatement (Third) of Torts: Products Liability, § 1, Reporters' Note, cmt. A (collecting authorities). New Hampshire law is in accord with this consensus and distinguishes among defects in manufacturing, design, and warnings. *See, e.g.*, *LeBlanc v. Am. Honda Motor Co.*, 688 A.2d 556, 562 (N.H. 1997).

Contrary to Petitioner's contention, this Court's decision last Term in *Kurns* did not equate failure-to-warn and design-defect claims. It simply held that both types of claims fell within the exclusively federal field of "regulating locomotive equipment," and thus were preempted.[2] Indeed, the Court's preemption discussion was careful to distinguish between, and separately analyze, the plaintiff's failure-to-warn and design-defect claims. 132 S. Ct. at 1268 (quoting *Restatement (Third) of Torts: Products Liability*, § 2(e), cmt. 1 for the proposition that "[r]easonable designs and instructions or warnings both play important roles in the production and distribution of reasonably safe products").

New Hampshire law recognizes this distinction. As the New Hampshire Supreme Court stressed in *LeBlanc*: "The plaintiff's design defect and failure to warn claims are separate." 688 A.2d at 562. The absence of an adequate warning is not an element of the strict liability design-defect cause of

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[2] The Court had long ago held that Congress, in enacting the Locomotive Inspection Act, had "manifest[ed] the intention to occupy the entire field of regulating locomotive equipment." *Napier v. Atlantic Coast Line R.R. Co.*, 272 U.S. 605, 611 (1926). In light of that long-standing precedent, the central issue in *Kurns* was whether the plaintiff's state-law claims implicated locomotive equipment in any way and thus fell within that preempted field.

action in New Hampshire (or anywhere else, for that matter).

To make out a design-defect claim in New Hampshire, a plaintiff must prove that

> (1) the design of the product created a defective condition unreasonably dangerous to the user;
>
> (2) the condition existed when the product was sold by a seller in the business of selling such products;
>
> (3) the use of the product was reasonably foreseeable by the manufacturer; and
>
> (4) the condition caused injury to the user or the user's property.

Vautour v. Body Masters Sports Indus., Inc., 784 A.2d 1178, 1181 (N.H. 2001) (citing *Chellman v. Saab-Scania AB*, 637 A.2d 148, 150 (1993)). "[W]hether a product is unreasonably dangerous . . . is determined by the jury using a risk-utility balancing test. Under [that test], a product is defective as designed 'if the magnitude of the danger outweighs the utility of the product.'" *Id.* at 1182 (quoting William Lloyd Prosser, *et al.*, *Prosser and Keeton on the Law of Torts* § 99, at 699 (5th ed. 1984)). The district judge's instructions to the jury in this case required them to find each of these elements. J.A. 538.

That the product at issue in this case was a prescription drug does not alter this analysis. Contrary to Petitioner's assertion, Pet'r's Br. 34-35, comment k to the *Restatement (Second) of Torts* § 402A, does not convert design-defect claims involving unreasonably dangerous drugs into failure-to-warn claims.[3]

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[3] Comment k provides, in full:

> k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it,

Any discussion of the implications of comment k is irrelevant in this case, given that Mutual expressly waived its comment k defense before trial. Pet. App. 7a. In any event, Petitioner misunderstands comment k.

Comment k applies only to "unavoidably unsafe" products and exempts them from strict liability, so long as they are "properly prepared, and accompanied by proper directions and warning." *Restatement (Second) of Torts* § 402A, cmt. k. An "unavoidably unsafe" product is "an apparently useful and desirable product, attended with a known but apparently reasonable risk," *id.*, that is, a product with utility that outweighs its risks. Thus, by definition, an "unreasonably dangerous" product—one with risks that exceed its utility—cannot be an "unavoidably unsafe" one.

In the vast majority of states, including New Hampshire, the comment k defense must be applied on a case-by-case basis; it does not afford blanket design-defect immunity to all prescription drugs. *See Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 655 (1st Cir. 1981) ("We are unwilling to say that under New Hampshire's balancing test no drug can ever be classified as unreasonably dangerous.").[4] In *Toner v.*

> is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A, cmt. k (1965).

[4] Only three states appear to apply comment k to all prescription drugs: California, Utah, and Washington. *See*

Lederle Laboratories, 732 P.2d 297 (Idaho 1987), the Idaho Supreme Court explained the reasons for case-by-case application of comment k:

> The comment refers to *'some'* products which are unavoidably unsafe; . . . the comment cites certain examples from that field deserving of its protection and notes that '[t]he same is true of *many* new or experimental drugs . . .' Obviously, the comment does not apply to *all* drugs. Rather, the comment applies 'when the situation calls for it,' which is when the product is unavoidably unsafe, but is 'an apparently useful and desirable product, attended with a known but apparently reasonable risk' . . . . It is equally obvious that not all drugs are so perfectly designed that they cannot be made more pure or more safe, or that there are not safer, suitable alternatives; nor do the benefits of all drugs necessarily outweigh their risks.

Id. at 308. Thus, where a jury finds that a drug is unreasonably dangerous, comment k does not apply and, therefore, design-defect liability may be imposed even if the drug was "properly prepared, and accompanied by proper directions and warnings."

Brown v. Superior Court, 751 P.2d 470 (Cal. 1988); *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991); *Young v. Key Pharms.*, 922 P.2d 59 (Wash. 1996) (en banc).

B. An Adequate Warning Does Not Automatically Shield an Unreasonably Dangerous Product From Design-Defect Liability.

Indeed, even where a defendant provides an ideal warning, it may still be held strictly liable when the product's risks outweigh its benefits. Warnings are not an adequate substitute for supplying a reasonably safe product.

To begin with, "instructions and warnings may be ineffective because users of the product may not be adequately reached, may be likely to be inattentive, or may be insufficiently motivated to follow the instructions or heed the warnings." *Restatement (Third) of Torts: Products Liability* § 2, cmt. l. Moreover, some products will remain unreasonably dangerous even when warnings are followed. In the drug context, for example, certain side effects will occur in some number of cases even when all instructions for safe use and warnings are heeded. If the risks posed by those side effects are found to outweigh the drug's benefits to the public as a whole, then the manufacturer will be obligated to compensate the injured patient, regardless of the presence of warnings regarding those risks.

This is not to say that the warnings provided by a manufacturer are always irrelevant to a claim of strict liability design defect. In some cases, an effective warning, by potentially alerting consumers (or, in the case of prescription drugs, prescribing physicians) about a product's dangers, can reduce those risks; on occasion, a warning or instruction for safe use might even shift the overall risk-utility balance from unreasonably dangerous to reasonably

so. For this reason, New Hampshire law identifies "the presence and efficacy of a warning to avoid an unreasonable risk of harm" as one of the factors that a jury may evaluate to determine whether a product is unreasonably dangerous. *Price v. BIC Corp.*, 702 A.2d 330, 333 (N.H. 1997).

As the district court recognized, however, a warning can only ameliorate the risks inherent in a product's design; it cannot increase them. If a product's design is not unreasonably dangerous without any warning, it cannot become unreasonably dangerous when a warning (however inadequate) is added. Evidence of warning can therefore only aid a defendant in a design-defect claim. Thus, the district court's repeated admonition that Ms. Bartlett "needed to prove that sulindac's risks outweighed its benefits '*despite* its warning, not *because* of it." Pet. App. 37a (emphasis in original) (quoting *Bartlett v. Mutual Pharm. Co.*, No. 08-cv-00358-JL, 2010 WL 3303864, at *1 (Aug. 15, 2010)). And, when it came time to instruct the jury, the district court was careful to emphasize this distinction:

> The warning. If you determine that sulindac was unreasonably dangerous, you may consider the presence and efficacy (or effectiveness) of a warning *to avoid an unreasonable risk of danger* from foreseeable uses of the product. The plaintiff must prove that the product was unreasonably dangerous *even with its warning*.

J.A. 539 (emphasis added).

Assuming, as we must, that the jury followed the court's instructions, *see Marshall v. Lonberger*, 459 U.S. 422, 438 n.6 (1983) ("the crucial assumption underlying the system of trial by jury is that juries will follow the instructions given them by the trial judge") (internal quotations and citations omitted), it could not have found Mutual liable due to inadequacies in the warnings it provided. The jury held Mutual liable for defective design, not for failing to provide an adequate warning.

II. STATE – LAW DESIGN - DEFECT LIABILITY FOR PRESCRIPTION DRUGS COMPLEMENTS AND SUPPORTS THE FDA REGULATORY SYSTEM.

A. Just as in *Wyeth v. Levine*, State Design-Defect Liability Is Consistent With the Purposes of the FDCA.

Just like the failure-to-warn claim in *Levine*, the strict liability design-defect cause of action at issue in this case is entirely consistent with—and complementary to—the federal regulatory scheme. In *Levine*, this Court articulated the ways in which state law complements federal law:

> The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to

> disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. . . . Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

555 U.S. at 578-79; *see also id.* at 574 ("state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs").

Each of these arguments is equally applicable to strict liability design claims. The FDA's resources remain limited, and it must of necessity rely on manufacturers—both brand-name and generic—to alert the agency when new information indicates that a drug's risks are greater, or that it is less effective, than previously understood.[5] State product-liability claims help expose such risks and provide powerful incentives for drug manufacturers to address these dangers, by bringing the matter to the FDA's attention, pursuing strengthened labeling, or by withdrawing unreasonably dangerous products from the market. In so doing, state tort law directly supports and complements the federal regulatory system. And, of course, design-defect liability also provides critically important compensation to

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[5] Although Congress expanded the FDA's powers to order post-approval studies, clinical trials, and/or labeling changes in 2007, 21 U.S.C. § 355(o) (Supp. V 2011), the agency still needs to be made aware of an emerging risk before it can address it. In any event, Ms. Bartlett's injury predated this statutory change.

persons injured by unreasonably dangerous drugs such as Karen Bartlett.

B. As the United States Acknowledges, Such State-Law Actions Largely Parallel the FDCA's Prohibition on the Sale of Misbranded Drugs.

Significantly, the standards for design-defect liability under state law largely parallel federal requirements governing prescription drugs. The United States acknowledges in its amicus brief that the FDA itself employs a risk-utility balancing test in deciding whether to approve a drug:

> Because "[n]o drug is absolutely safe" and "all drugs have side effects," FDA "generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use," *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979), *i.e.*, the drug's "probable therapeutic benefits must outweigh its risk of harm," *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000).

U.S. Amicus Br. 3 (first internal citation omitted). That inquiry parallels the risk-benefit analysis used to determine whether a product is unreasonably dangerous and, therefore, whether the manufacturer is strictly liable under state law for injuries caused by that product.

FDA approval of a drug is based on the risk and benefit information available to the agency at the time. It does not give the manufacturer "the unfettered right, for all time, to market its drug."

Levine, 555 U.S. at 592 (Thomas, J., concurring in the judgment). New information that emerges after the drug enters the market may indicate that the drug is actually ineffective or unsafe.[6] If such information switches the risk-utility balance, *i.e.*, leads to the conclusion that the drug is unreasonably "dangerous to health when used" in accordance with its approved labeling, the drug becomes "misbranded" under federal law, 21 U.S.C. § 352(j). And federal law prohibits the sale of any misbranded drug. 21 U.S.C. §§ 331(a)-(c), (g), and (k).[7]

The United States concedes that a state design-defect cause of action that imposed liability on such misbranded drugs would not conflict with federal law. U.S. Amicus Br. 23. That is precisely the cause of action at issue here. The United States

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[6] As this Court explained in *Levine*, in discussing the 2008 amendment to the FDA's "changes being effected" regulation, such new information is not limited to new data, but also encompasses "new analyses of previously submitted data." The rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments: "[I]f the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for 'newly acquired information.'" 555 U.S. at 569 (quoting [illegible] Fed. Reg. 49603, 49604, 49607 (Aug. 22, 2008)).

[7] This is exactly what happened with propoxyphene. New evidence of propoxyphene's risks emerged after the drug was marketed. This new evidence eventually led the FDA to reevaluate propoxyphene's risk-utility balance and ultimately to conclude that "the safety risks of propoxyphene outweigh its benefits." *See FDA Drug Safety Communication*, *supra*. It therefore called upon all manufacturers of propoxyphene to stop selling the drug. *Id.*

identifies no difference between the federal misbranding standard set forth in the statute and the "unreasonably-dangerous" analysis followed in New Hampshire and prescribed in the jury instructions in this case.

Moreover, in evaluating a product's risks, state law gives weight to the FDA's role in reviewing drug safety. States generally adhere to the basic tort principle, in negligence cases, that compliance with applicable regulatory requirements is relevant evidence that a defendant's conduct was not negligent; however, such evidence is not conclusive of non-liability where circumstances exist that would have led a reasonable manufacturer to take additional precautions. *See Restatement (Second) of Torts* § 288C (1965) ("Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions."); *id.*, cmt. *a*. ("Where there are no such special circumstances, the minimum standard prescribed by the legislation or regulation may be accepted by the triers of fact, or by the court as a matter of law, as sufficient for the occasion; but if for any reason a reasonable man would take additional precautions, the provision does not preclude a finding that the actor should do so.").

Similarly, in the strict liability context, compliance with regulatory requirements can be relevant evidence that a product is not defective. *See Raymond v. Riegel Textile Corp.*, 484 F.2d 1025 (1st Cir. 1973) (applying New Hampshire law). The district judge so instructed the jury in this case. J.A. 541.

The jury was well aware that the FDA had approved sulindac (and its label). But Plaintiff presented the jury with significant evidence of sulindac's risks that became available only after sulindac had been approved and that had not been given to the FDA. Resp't's Br. 52. That evidence provided a more than sufficient basis for the jury to conclude that, despite the earlier FDA approval, sulindac was unreasonably dangerous at the time Karen Bartlett used the drug.

The United States now implies that all of that new information was considered by the FDA in its 2005 review of all NSAID products. U.S. Amicus Br. 7. Even if that were true,[8] Petitioner never argued that that 2005 FDA review should have been given preemptive effect. *See* Pet. App. 69a-76a (identifying

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[8] There is reason to doubt the FDA's description of its 2005 review as a "'comprehensive review of the risks and benefits, including the risk of SJS and TEN, of all NSAID products.'" U.S. Amicus Br. 7 (quoting FDA, *Decision Letter*, FDA Docket No. 2005P-0072/CP1, at 2 (June 22, 2006), *available at* http://www.fda.gov/ohrms/dockets/dockets/05p0072/05p-0072-pav0001-vol1.pdf). The 2005 review concerned the cardiovascular risk of non-steroidal anti-inflammatory drugs ("NSAIDs"), not their risk of skin reactions such as SJS/TEN. *See* Memorandum from John K. Jenkins, M.D., Director, Office of New Drugs to Steven Galson, M.D., Acting Director, Center for Drug Evaluation and Research re: Analysis and Recommendations for Agency Action Regarding Non-steroidal Anti-inflammatory Drugs and Cardiovascular Risk (Apr. 6, 2005), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm106201.pdf. While the 2005 review did consider the reporting rate of SJS/TEN associated with Bextra (valdecoxib), as compared to the rate for other Cox-2 selective agents, there is no indication that the study considered the risk of SJS/TEN associated with non-selective NSAIDs such as sulindac. *See* Resp't's Br. 52-54.

preemption arguments raised by Mutual). Since preemption is an affirmative defense, the burden was on Mutual to raise a defense based on the 2005 NSAID review; its failure to do so means that any such argument has been waived.

C. Mutual's Argument that Design-Defect Liability "Thwarts Hatch-Waxman's Central Objective of Ensuring that Generic Drugs Are Available for Sale" Completely Misses the Point.

Mutual itself raises a different obstacle preemption argument. It argues that imposing state tort liability upon it for the sale of an unreasonably dangerous drug frustrates Congress's "central objective" in enacting Hatch-Waxman of "ensur[ing] that generic copies of previously approved drugs are available for sale." Pet'r's Br. 46; *see generally id.* at 45-53.

Petitioner's argument completely misses the point. A determination that a particular drug product is unreasonably dangerous applies equally to both branded and generic versions of that drug. *Cf.* U.S. Amicus Br. 30 ("brand-name and generic drugs should be treated the same for purposes of design-defect claims"). When Congress enacted Hatch-Waxman, it undoubtedly wanted to encourage the availability of less expensive generic versions of safe and effective drug products. But there is no reason to believe that Congress had any desire to encourage—let alone ensure—the sale of unreasonably dangerous prescription drugs, whether in branded or generic form. Indeed, the misbranding provisions of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§

331, 352(j), demonstrate that the opposite is true. So imposing state law liability for injuries caused by an unreasonably dangerous generic drug is not in conflict with congressional purposes.

III. IT WAS NOT IMPOSSIBLE FOR PETITIONER TO COMPLY WITH BOTH STATE AND FEDERAL LAW.

Finally, as the Court of Appeals recognized, it was quite possible for Mutual to comply with both state and federal law by not selling sulindac. Pet. App. 10a-11a. Therefore, there is no impossibility preemption here.

This Court has always held that conflict preemption based on impossibility is very narrowly circumscribed. The party arguing for preemption must establish that "compliance with both federal and state [law] is a physical impossibility." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). Physical impossibility only occurs where federal law prohibits conduct that state law requires, or vice versa. *See Barnett Bank of Marion Cnty., N.A., v. Nelson*, 517 U.S. 25, 31 (1996) (two statutes would "impose directly conflicting duties on national banks . . . if the federal law said, 'you must sell insurance,' while the state law said, 'you may not.'"). There is no physical impossibility if either law is permissive. *Michigan Canners and Freezers Ass'n, Inc. v. Agricultural Marketing and Bargaining Board*, 467 U.S. 461, 478 n.21 (1984) ("Because the [state statute] is cast in permissive rather than mandatory terms . . . this is not a case in which it is impossible for an individual to comply with both state and federal law.").

In *Mensing*, this Court added a qualification to this test: finding impossibility where federal law prohibits the defendant from "independently" complying with state law without intervening government action. 131 S. Ct. at 2579 ("The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it.").[9]

In this case, federal law did not prohibit Mutual from complying with state law. Nothing in federal law prohibits Mutual from complying with the district court's judgment and compensating Ms. Bartlett for her injuries caused by Mutual's drug. Even if state law were understood to impose a duty not to sell unreasonably dangerous products—as opposed to a duty to pay compensation for injuries caused by unreasonably dangerous products—compliance with federal and state law would not be impossible. Federal law did not require Mutual to sell its generic sulindac, in New Hampshire or anywhere else. *See* U.S. Amicus Br. 21 (FDCA "does not expressly require that an approved drug be made available in any particular State or that the manufacturer be guaranteed the ability to make it so."). Drug manufacturers are generally free to decide to stop selling an approved drug at any time, whether due to safety concerns or for other reasons. *See, e.g.*, 21 C.F.R. § 314.161 (governing FDA actions

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[9] This Court found impossibility in *Mensing* because federal law prohibited generic drug companies from adding new warnings to their labels without prior FDA action, and it was "not dispute[d] that . . . state law required the Manufacturers to use a different, safer label." *Id.* at 2574. "Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." *Id.* at 2578.

following a manufacturer's voluntary withdrawal of a listed drug).[10] As the Court of Appeals recognized, Mutual could have independently complied with both state and federal law by not selling sulindac. Pet. App. 10a-11a (Mutual "certainly can choose not to make the drug at all;" "the decision to make the drug and to market it in New Hampshire is wholly its own"). Because compliance with both laws was not impossible, Karen Bartlett's design-defect claim should not be preempted.

CONCLUSION

For the foregoing reasons, *amici curiae* John and Tammy Gilbert, Deborah Kinter, Donald Brown, and Alice Szromba urge this Court to affirm the judgment of the Court of Appeals.

February 20, 2013 Respectfully submitted,

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[10] Federal law only restricts a drug company's ability to withdraw from the market where it "is the sole manufacturer of a drug that is life-supporting; life sustaining; or intended for use in the prevention of a debilitating disease or condition." 21 U.S.C. § 356c. That provision does not apply here.

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AMICUS CURIAE BRIEF

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IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF AMICI CURIAE SENATOR TOM HARKIN AND REPRESENTATIVE HENRY A. WAXMAN IN SUPPORT OF RESPONDENT

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INTEREST OF AMICI CURIAE[1]

This brief is submitted on behalf of amici curiae Senator Tom Harkin and Representative Henry A. Waxman, both members of Congress with an interest in the important issue presented in this case. Senator Harkin and Representative Waxman have extensive knowledge of pharmaceutical regulation under the Food, Drug, and Cosmetic Act (FDCA) and the Hatch-Waxman Amendments.

Senator Harkin has served in the United States Congress since 1975, first as a member of the House of Representatives and, since 1985, as a member of the Senate. He is the current chair of the Senate Committee on Health, Education, Labor & Pensions, the jurisdiction of which encompasses the Food and Drug Administration (FDA). Senator Harkin is also a member of the Senate Appropriations Committee, where he serves as a member of the subcommittee with jurisdiction over FDA funding and as chair of the Labor, Health and Human Services, and Education subcommittee, which has jurisdiction over many other programs of the Department of Health and Human Services.

Representative Waxman has served in the House of Representatives since 1974. He is currently Ranking Minority Member of the House Energy and Commerce Committee, the jurisdiction of which includes health care

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[1] Pursuant to Rule 37.6 of this Court, amici curiae states that this brief was not written in whole or in part by counsel for a party and that no one other than amici curiae or their counsel made a monetary contribution to the preparation or submission of this brief. Letters from both parties consenting to all amicus briefs are on file with the Clerk.

policy, regulation of prescription drugs and the pharmaceutical industry, and consumer protection, all of which are implicated by this case. Representative Waxman, long a leader on health issues, was one of the two principal sponsors of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the Hatch-Waxman Amendments. In addition, in 2008, Representative Waxman presided over legislative hearings concerning preemption under the FDCA.

Because preemption is a question of congressional intent, *see Wyeth v. Levine*, 555 U.S. 555, 565 (2009), amici are well situated to address the question presented in this case. Although amici submit this brief in their individual capacities, not on behalf of Congress, their views are informed by their experiences as Members of Congress.

SUMMARY OF ARGUMENT

This Court has often stated that preemption turns on congressional purpose. Neither the text nor the purpose of the FDCA or the Hatch-Waxman Amendments requires preemption of state-law design-defect claims brought by injured patients against prescription drug manufacturers.

The FDCA is a consumer protection statute, in existence for decades in largely its current form. During those decades, state-law claims against prescription drug manufacturers have been frequent, yet petitioner offers no evidence that such claims have created a dilemma for manufacturers, interfered with federal regulation, or undermined statutory objectives. During those same years, Congress enacted express preemption provisions with respect to other FDA-regulated products, but declined to do so with respect to prescription drugs, despite specific

consideration of the issue. In particular, Congress's decision expressly to save product liability claims from the scope of an express preemption provision applicable to over-the-counter drugs, which, like brand-name and generic drugs, the FDA allows to be marketed based on a risk-benefit analysis, demonstrates that state-law design claims do not interfere with the achievement of Congress's purposes in enacting the FDCA.

Likewise, state-law design-defect claims pose no threat to the goal of the Hatch-Waxman Amendments. In Hatch-Waxman, Congress sought to reduce anticompetitive barriers to the marketing of generic drugs. Although tort claims long preceded the 1984 Amendments, Congress said nothing during the legislative debate to suggest that it viewed claims brought by injured patients as such a barrier. The nearly 30 years since enactment of the Hatch-Waxman Amendments have shown that understanding to be correct: Despite the continued existence of lawsuits by injured patients, generics' share of the prescription drug market has dramatically increased.

Although neither the FDCA nor the Hatch-Waxman Amendments evinces an intent to preempt state-law design claims, the decision to preempt remains within Congress's authority. The Court should leave that policy decision to Congress.

ARGUMENT

I. Federal Regulation of Prescription Drugs Does Not Preempt State-Law Design-Defect Claims.

A. Drug Regulation Under the FDCA Does Not Preempt State Common Law.

Petitioner and the Solicitor General argue that FDA approval of a prescription drug preempts state-law design-defect claims, barring an injured patient from pur-

suing compensation from the drug's manufacturer, whether the drug at issue is a brand-name drug or a generic. Four years ago, this Court considered and rejected a similar argument that regulation under the FDCA establishes both a floor and a ceiling for drug regulation, such that allowing a state-law remedy for injuries caused by a prescription drug would obstruct the purposes and objectives of federal regulation. As the Court said at that time, "[t]he most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary." *Wyeth v. Levine*, 555 U.S. 555, 574 (2009).

The FDCA, as the Court has explained, was enacted "to bolster consumer protection against harmful products." *Id.* (citing *Kordel v. United States*, 335 U.S. 345, 349 (1948), & *United States v. Sullivan*, 332 U.S. 689, 696 (1948)). But in enacting this consumer protection law in 1938, Congress did not create a federal remedy for consumers harmed by unsafe or ineffective drugs. To the contrary, Congress rejected a provision that would have created a federal damages remedy, *see* H.R. 6110, 73d Cong., 1st Sess. § 25 (1933), specifically because state common law already provided that remedy. *See Wyeth*, 555 U.S. at 574 & n.7. Indeed, "[c]ourts entertained tort suits against [drug] manufacturers since well before the passage" of the FDCA, and such litigation has long been a "common feature of the legal landscape." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 441 (2005) (discussing pesticides). Legislating against this backdrop, Congress may well have "recognized that state-law remedies further consumer protection by motivating manufacturer to produce safe and effective drugs and to give adequate warnings." *Wyeth*, 555 U.S. at 574.

Although the drug provisions of the FDCA have been amended many times since 1938, including significant

amendments in 1962, 1984, 1997, 2007, and 2012, arguments that product liability suits (whether based on design or labeling) against drug manufacturers were preempted by the FDCA were seldom made and, until the mid-2000s, rarely successful.[2] Significantly, in 1962, when Congress amended the FDCA to require, for the first time that drug manufacturers demonstrate effectiveness, in addition to safety, prior to receiving marketing approval, *Wyeth*, 555 U.S. at 567, Congress addressed preemption only to state that the new provisions do not preempt state law.[3]

Later, beginning in 1976, Congress enacted provisions expressly preempting categories of state laws with respect to other FDA-regulated products, including foods, medical devices, and cosmetics. *See* 21 U.S.C. §§ 343-1(a), 360k(a), & 379s. As these preemption provisions reflect, Congress has been particularly attentive to federalism concerns in connection with regulation under the FDCA and has crafted provisions to address these concerns where, in Congress's view, those changes were appropriate. Yet Congress never enacted an express preemption provision concerning prescription drugs.

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[2] *See, e.g., Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 537 (6th Cir. 1993) (no preemption); *Osburn v. Anchor Labs.*, 825 F.2d 908, 911-13 (5th Cir. 1987) (same); *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986) (same); *Feldman v. Lederle Labs.*, 592 A.2d 1176, 1195-97 (N.J. 1991) (same).

[3] *See* Pub. L. No. 87-781, § 202 (1962) ("Nothing in the amendments made by this Act to the federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.").

much less a provision directed at state-law damages suits.

Furthermore, in 1997, when Congress enacted an express preemption provision concerning over-the-counter (OTC) drugs, it explicitly provided that state product liability law would not be affected. *See* 21 U.S.C. § 379r(e) ("No Effect on State Product Liability law—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."). Yet there are no differences between OTC and prescription drugs that would warrant a different rule for preemption of product liability claims: For both kinds of drugs, the FDA's risk-benefit analysis has, since 1962, been a prerequisite to marketing.

Importantly, the same new drug application (NDA) process by which the FDA evaluates new prescription drugs before they can be marketed applies to new OTC drugs that are not covered by a monograph. *See* FDA, *Drug Applications for Over-the-Counter Drugs* (Oct. 18, 2012).[4] For other OTC drugs, the FDA develops a monograph, which is "a kind of 'recipe book' covering acceptable ingredients, doses, formulations, and labeling" for a particular drug. *Id.*; *see* 21 C.F.R. § 330.10. After the FDA publishes a drug monograph, any manufacturer can sell that OTC drug if it follows the "recipe"—a situation analogous for present purposes to approval of an abbreviated new drug application (ANDA) for a generic prescription drug, which must follow a brand-name product

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[4] *At* http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm.

in terms of active ingredients, dosage form, labeling, and other characteristics. *See* 21 U.S.C. § 355(j). Although the FDA does not review individually each OTC monograph drug as it does each generic drug, both types of drugs must meet FDA-required specifications (as set forth either in the monograph or through the brand-name drug) that are based on the FDA's weighing of risks and benefits.

The fact that some drugs, for example, Claritin and Zyrtec, begin as prescription drugs and are later switched to OTC, *see* 21 C.F.R. § 310.200, further reveals the illogic of the preemption argument in this context. Again, not only has Congress never passed a provision to preempt state-law damages claims concerning OTC drugs, it expressly provided in § 379r(e) that these claims are not preempted.

This Court has repeated time and again that "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth*, 555 U.S. at 565.[5] The OTC provision explicitly carving out product liability suits from the scope of an express preemption provision evinces Congress's understanding that those suits pose no obstacle to the purpose of federal regulation of OTC drugs. Rather, Congress has made plain that state product liability law should coexist with federal approval of such drugs.

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[5] *See also, e.g., Altria Group v. Good*, 555 U.S. 70, 76 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992); *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978); *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963).

Moreover, the FDA licenses vaccines through a premarket review process that is similar to the review process for new drugs. *See* 42 U.S.C. § 262(j); 21 C.F.R. § 601; FDA, *Vaccine Product Approval Process* (updated June 18, 2009). In 1986, Congress enacted the National Childhood Vaccine Injury Act, which provides a federal remedy for vaccine-related injuries as a substitute for state damages actions, 42 U.S.C. § 300aa-21(a), "[t]o stabilize the vaccine market and facilitate compensation." *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011). This Court recently held that the Act's express preemption provision preempts design-defect claims. *Id.* at 1075 (discussing 42 U.S.C. § 300aa–22(b)(1)). But the premise underlying the Court's discussion, like the premise under which Congress operated in enacting the Vaccine Act, is that, absent that Act, such claims would not be preempted. The Vaccine Act thus confirms that, in Congress's view, FDA regulation of drugs does not preempt state-law design-defect claims where preemption is not specifically provided by federal statute.

Notably, although FDA approval is not a basis for preemption, the approval nonetheless plays an important role in design-defect cases. Under traditional tort law, federal approval of a product for marketing and compliance with federal requirements for product safety plays a role, often a very powerful role, in product liability cases. Consistent with this tradition, the current law in most states allows a manufacturer that is alleged to have sold a defective product to use compliance with federal standards or regulations as non-dispositive evidence that the product was not defective or that the manufacturer acted non-negligently. *Restatement (Third) of Torts* § 4(b) (1998); *accord* 63B *Am. Jur. 2d Products Liability* § 2022 (2008) ("As a general rule, compliance with appli-

cable federal standards is relevant but not conclusive evidence in a products liability case.").[6]

In sum, the notion that FDA regulation broadly preempts design-defect claims against prescription drug manufacturers finds no support in the text or purpose of the FDCA, runs counter to the OTC provision addressing product liability law, and ignores more than 75 years of history in which damages suits and federal drug approval have co-existed.

B. The Hatch-Waxman Amendments Do Not Support Preemption of Design-Defect Claims Concerning Generic Drugs.

In addition to asserting that the FDCA preempts design-defect claims against both brand-name and generic drug manufacturers, petitioner and the Solicitor General argue that preemption of such suits against generic drug manufacturers is essential to fulfilling the purposes of the Hatch-Waxman Amendments, which created the current system for FDA approval of generic replacements for brand-name drugs. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417,

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[6] *See, e.g.*, Ind. Code § 34-20-5-1; Kan. Civ. Proc. Code Ann. § 60-3304; Tenn. Code Ann. § 29-28-104; Utah Code Ann. § 78B-6-703(2); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (North Carolina law); *O'Neill v. Novartis Consumer Health, Inc.*, 55 Cal. Rptr. 3d 551, 557 (Cal. Ct. App. 2007); *Wagner v. Clark Equip. Co.*, 700 A.2d 38, 50 (Conn. 1997); *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 675 (Ga. 1994); *Toner v. Lederle Labs.*, 732 P.2d 297, 311 n.12 (Idaho 1987); *Malek v. Lederle Labs.*, 466 N.E.2d 1038, 1039–40 (Ill. App. Ct. 1984); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70–71 (Mass. 1985); *Brooks v. Beech Aircraft Corp.*, 902 P.2d 54, 63 (N.M. 1995); *Sherman v. M. Lowenstein & Sons, Inc.*, 282 N.Y.S.2d 142, 143–44 (N.Y. App. Div. 1967); *Zacher v. Budd Co.*, 396 N.W.2d 122, 133–34 (S.D. 1986).

98 Stat. 1585. As all parties seem to agree, the Hatch-Waxman Amendments were intended to foster the speedy availability of generic versions for brand-name drugs, so that the resulting competition would lower prices for consumers. Congress sought to achieve this purpose, however, by eliminating regulatory and patent-based barriers to the approval and marketing of generic drugs, not by eliminating remedies for patients injured by defective drugs.

1. The Hatch-Waxman Amendments aimed "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H.R. Rep. No. 98-857, Pt. 1, at 14 (June 21, 1984). The Amendments reflect congressional dissatisfaction with then-existing FDA procedures for approval of generic drugs, which required generic drug manufacturers to obtain approval of their products as if they were completely new drugs, including through new clinical studies of safety and effectiveness, although the generic versions were the same as brand-name drugs that the FDA had already approved. This time-consuming and expensive process, which could only be initiated after patents protecting the brand-name drug expired, "had serious anti-competitive effects," and resulted in "the practical extension of the monopoly position of the patent holder beyond the expiration of the patent." H.R. Rep. No. 98-857, Pt. 2, at 4 (Aug. 1, 1984).

Through the ANDA procedure, 21 U.S.C. § 355(j), which speeds a generic's entry onto the market, the Hatch-Waxman Amendments sought to combat these anticompetitive effects and to "implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent" on the original drug. H.R. Rep. No. 98-857,

Pt. 2, at 9. To achieve these goals, the Amendments allow the FDA to approve a generic drug based on a showing of bioequivalence to an approved drug without requiring additional clinical testing for safety and effectiveness, and to do so "before the patent on the drug has expired" if the generic manufacturer alleges "that the existing patent is invalid or will not be infringed." *Id.* at 5. In this manner, Congress in the Hatch-Waxman Amendments sought to achieve the ultimate objective of protecting consumers by "provid[ing] low-cost, generic drugs for millions of Americans," resulting in "a significant savings to people who purchase drugs." 130 Cong. Rec. 24427 (Sept. 6, 1984) (statement of Rep. Waxman).

At the same time, as this Court has repeatedly stated, "[n]o legislation pursues its purposes at all costs." *Freeman v. Quicken Loans*, 132 S. Ct. 2034, 2044 (2012) (quoting *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987)). Indeed, it "frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers [a] statute's primary objective must be the law." *Norfolk Southern Ry. v. Sorrell*, 549 U.S. 158, 171 (2007) (quoting *Rodriguez*, 480 U.S. at 526). A congressional intent to combat delays in the introduction of generic drugs is not equivalent to a purpose "to end every possible delay at all costs." *Holland v. Florida*, 130 S. Ct. 2549, 2562 (2010).[7]

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[7] The terms of Hatch-Waxman make clear that Congress did not place immediate introduction of generic drugs above all other considerations. The legislation, for example, provides for a stay of approval of a generic manufacturer's ANDA upon the institution of patent infringement proceedings by a brand-name manufacturer; allows a successful infringement action by the brand-name manufacturer to keep the generic substitute off the market; and gives the

(*Footnote continued*)

In particular, Congress's policy of promoting the availability of lower-cost drugs to consumers by eliminating legal barriers to competition between generic and brand-name manufacturers does not imply a policy of eliminating other legal constraints (applicable equally to generic and brand-name manufacturers) that help to protect consumers against unsafe drugs and that offer remedies when consumers are injured by such drugs. Indeed, the legislative history of the Hatch-Waxman Amendments nowhere suggests that Congress viewed tort liability as a barrier to the introduction of generic drugs, much less a barrier comparable to those posed by existing FDA procedures and patent doctrines. Tort liability is not mentioned in the reports and debates concerning the Hatch-Waxman Amendments, nor is there any hint that Congress was concerned that product-liability suits would impede the rapid introduction of generic substitutes for brand-name drugs that Congress anticipated would result from the Amendments.

Tort liability for manufacturers of FDA-approved drugs was well established at the time Congress enacted the Hatch-Waxman Amendments. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 340 & n.11 (2008) (Ginsburg, J., dissenting) ("in 1976, state common-law claims for drug labeling and design defects had continued unabated despite nearly four decades of FDA regulation" (citing cases)). In the face of this legal background, as well as Congress's inclusion of an express preemption provision in the Medical Device Amendments of 1976, Congress's complete silence with respect to the subject in the Hatch-

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first generic manufacturer to submit an ANDA a period of exclusivity in which no other generic manufacturer may enter the market. *See* 21 U.S.C. §§ 355(j)(5)(B)(iii), (iii)(II), (iv).

Waxman Amendments and the proceedings leading to their enactment is telling. As in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), it is "difficult to believe that Congress would, without comment, remove all means of judicial recourse" for consumers injured by generic drugs in a statute aimed at other objectives altogether. *Id.* at 251. Far from supporting a broad claim of implied preemption, the background, purposes, and history of the Hatch-Waxman Amendments stand as strong "evidence that Congress did *not* regard state tort litigation as an obstacle to achieving its purposes." *Wyeth*, 555 U.S. at 575 (emphasis added).

2. The notion that product liability claims against generic drug manufacturers would thwart the realization of the objectives of the Hatch-Waxman Amendments is also unsupported by the history of the Amendments' implementation. As Congress foresaw, the Hatch-Waxman Amendments brought about an almost immediate transformation of the marketplace for prescription drugs. The Amendments have produced a remarkable influx of generic drugs into the marketplace, notwithstanding the absence, until very recently, of significant precedential support for the idea that lawsuits for injuries caused by defective drugs might be preempted.

Thus, in little more than 15 years after Hatch-Waxman's enactment, generic drugs' share of the prescription drug market grew from only 19 percent of all prescriptions to nearly half, saving consumers and the government trillions of dollars.[8] The market for generic

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[8] GAO, *Drug Pricing: Research on Savings from Generic Drug Use* 2 (2012), *at* www.gao.gov/assets/590/588064.pdf; 149 Cong. Rec. S8187 (June 19, 2003) (Statement of Sen. Kohl) (generic drugs accounted for 45% of prescriptions in 2001).

drugs flourished despite the almost total absence of case law indicating that lawsuits against drug manufacturers might be preempted by federal law. *See Riegel*, 552 U.S. at 342, & n. 19 (Ginsburg, J., dissenting) (noting courts' overwhelming rejection of preemption claims in cases involving prescription drugs between 1976 and 2008). More recently, with the issue unsettled, the market share of generic drugs has continued to increase, with approximately 80 percent of all prescriptions now filled by generic drugs.[9] Meanwhile, the prices of generic drugs have steadily fallen, both in real and nominal dollars.[10] If potential tort liability has posed an obstacle to achievement of the purposes of the Hatch-Waxman Amendments, it has gone unnoticed in the marketplace.

II. The Decision Whether To Oust State Law Is Properly Left To Congress.

A. "Pre-emption analysis should not be a freewheeling judicial inquiry into whether a state statute is in ten-

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[9] *See* IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2011* at 26 (2012), www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf.

[10] *See* GAO, *Prescription Drugs: Trends in Usual and Customary Prices for Commonly Used Drugs*, at 18-19 (2011), *available at* gao.gov/assets/100/97284.pdf; Stephen W. Schondelmeyer & Leigh Purvis, *Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Medicare Beneficiaries 2005 to 2009*, at 3, 5 (2012), *at* www.aarp.org/content/dam/aarp/research/public_policy_institute/health/rx-pricewatch-march-2012-AARP-ppi-ealth.pdf; Express Scripts, *Drug Trend Quarterly* 15 (Nov. 2012), http://digital.turn-page.com/i/95262; GAO, *Prescription Drugs: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004*, at 4, 7 (2005), *available at* www.gao.gov/new.items/d05779.pdf.

sion with federal objectives, but an inquiry into whether the ordinary meanings of state and federal law conflict." *Wyeth*, 555 U.S. at 588 (Thomas, J., concurring) (internal quotation marks omitted). Here, the weighing of policy concerns that underlies the arguments in favor of preemption reflects exactly this "inherently flawed" approach to preemption. *Id.* at 594.

Congress is well aware of its authority to preempt state damages actions, and with respect to prescription drugs, as with OTC drugs, it has not done so. Moreover, in recent years, following litigation addressing whether federal regulation preempts state-law claims regarding injuries caused by drugs, both Chambers of Congress have considered preemption of state-law claims concerning drugs. Yet Congress has taken no action to change the historical framework through which state law controls whether injured patients have a tort remedy. *See Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?*, Hearing Before the Senate Committee on the Judiciary, 110th Cong. 1st Sess. (Sept. 12, 2007); *Should FDA Drug and Medical Device Regulation Bar State Liability Claims?*, Hearing Before the House Committee on Oversight and Government Reform, 110th Cong. 2d Sess. (May 14, 2008).

The decision whether to preempt state-law claims, for decades left to Congress, properly remains with Congress.

B. Inevitably, some patients will be injured by dangerous drugs, yet federal law provides no avenue for seeking compensation for such injury. Accordingly, preemption would cut off patients from even the possibility of holding a prescription drug manufacturer accountable for harm caused by a defective product. Preemption,

where accepted, leaves no room for factual distinctions between individual cases, sweeping away traditional common-law approaches to assessing liability.

Moreover, damages suits advance public health. Product liability lawsuits help to uncover information that can lead to safer products. Material produced in litigation can help the public and the FDA to identify problems with particular drugs and can add to physicians' and public understanding of the risks of the products and flaws in the regulatory system. *See, e.g.*, David Brown, *Maker of Vioxx Is Accused of Deception*, Wash. Post, Apr. 16, 2008, at A1 (discussing article from the *Journal of the American Medical Association* evaluating information found in Vioxx discovery documents); Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. Am. Med. Ass'n 308, 309 (2007) (offering several examples).

In addition, knowledge of a drug's risks, particularly long-term risks, is never complete at the time of initial marketing approval. Prior to approval, drugs are tested, on average, on between 600 and 3,000 patients. *See* Inst. of Med. of the Nat'l Acads., *The Future of Drug Safety: Promoting and Protecting the Health of the Public* 36 (2006), *available at* www.nap.edu/openbook.php?record_id=11750&page=R1IOM. Thus, "[a]n adverse event (even a serious one) that occurs in less than one in 1,000 patients cannot be reliably detected except in the largest premarket trials but can pose a serious public health problem when hundreds of thousands or millions of people use the drug." *Id.* at 37-38. In general, only half of a drug's serious hazards are known and documented in the *Physicians' Desk Reference* seven years after the drug's approval. *See* Karen Lasser, et al., *Timing of New Black*

Box Warnings and Withdrawals for Prescription Medications, 287 J. Am. Med. Ass'n 2215, 2218 (2002).

A number of prescription drugs—Darvon, Meridia, Vioxx, Bextra, Baycol, Rezulin, and Raptiva, to name a few—have been withdrawn from the market because experience showed that their risks outweighed their benefits. According to one article, 21 drugs were pulled from the U.S. market from 1995 to 2010, half because the drugs was linked to heart complications. The products had been on the market from as few as 11 months to as many as 30 years. Catherine Larkin, *Recalled Drugs Tied to Heart Risk Spurs Call for FDA Review*, Bloomberg (Sept. 28, 2010). Thus, design-defect claims based on post-approval experience with a drug do not "second-guess" (U.S. Br. 13.) the FDA.

Of particular relevance here, although the FDA will not approve an ANDA that references a brand-name drug no longer on the market without first determining whether the brand-name drug was discontinued for reasons of safety or effectiveness, 21 C.F.R. § 314.161, when a manufacturer voluntarily withdraws a brand-name drug from the market, the withdrawal does not preclude continued sale of already approved generic versions. For example, the manufacturer of Serzone, the brand-name antidepressant nefazodone, stopped selling the product in the U.S. 2004, after some countries had discontinued sales due to concerns that the drug caused severe liver damage. Yet several generic formulations of nefazodone are still available.[11]

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[11] *See* FDA, Drugs@FDA, www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name (showing brand-name Serzone "discontinued" and generic nefazo-

(*Footnote continued*)

Given that a drug's safety profile is incomplete at the time of approval, the possibility of product liability lawsuits helps to protect patients by serving as a powerful incentive for drug companies (both brand-name and generic, prescription and OTC) to improve products as soon as a defect is identified and to remove from the market older products that do not provide the safety of newer ones. Because, as a matter of both resources and operation of the statutory scheme, manufacturers have primary responsibility for ensuring the safety of their products, this incentive is vitally important for protecting patients from unsafe drugs.

The Solicitor General suggests an exception to its broad preemption theory in cases where state law requires a plaintiff to show that the manufacturer "knew or should have known of scientifically significant evidence that rendered the drug misbranded under federal law." U.S. Br. 22. But if the fact of approval preempts damages claims in the absence of such evidence, an injured patient will rarely have a chance to make that showing because, without discovery, patients are unlikely to have access to that evidence. *See supra* p. 16 (citing articles discussing cases in which litigation uncovered new information). And even if patients had such evidence, manufacturers sued under state law that requires such a showing often successfully argue that the showing is precluded as a species of "fraud-on-the-FDA" claim preempted under this Court's decision in *Buckman v. Plaintiff's' Legal Committee*, 531 U.S. 341 (2001). *See, e.g., Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 380 (5th Cir. 2012) (holding exception to Texas law bar-

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done hydrochloride still sold by three companies as prescription generic).

ring suits against drug companies in cases where company withheld or misrepresented information to FDA to be preempted); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965-66 (6th Cir. 2004) (holding exception to Michigan law barring suits against drug companies in cases where company misrepresented or withheld information that would have altered the FDA's decision to approve the drug to be preempted).

* * * * *

Petitioner and its amici have offered no evidence that the coexistence of state-law design-defect claims and FDA drug approval has posed any impediment to federal regulation, either since enactment of the FDCA in 1938, its amendment in 1962, or the Hatch-Waxman Amendments in 1984. In our legal tradition, the decision about whether and how to compensate individuals injured by products, including drugs, has been left to the states. In the absence of compelling evidence that Congress sought to alter that tradition, this Court should not reach out to do so.

CONCLUSION

For the foregoing reasons, the decision below should be reversed.

Respectfully submitted.

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AMICUS CURIAE BRIEF

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IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

ON WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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INTEREST OF THE AMICUS CURIAE[1]

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit corporation comprised of a broad range of American and international manufacturers; in addition, several hundred leading product liability defense lawyers are non-voting members.[2] PLAC seeks to develop and reform the law, with emphasis on product liability, so that it is fair and reasonable. To that end, PLAC submits amicus briefs in cases raising important legal issues to present the perspective of product manufacturers. PLAC's briefs have been accepted in over 975 cases, including in this Court.[3]

The jury verdict and district court judgment below found that a generic prescription drug manufactured by defendant was defectively designed under New Hampshire product liability law, and hence unlawfully marketed in the state, because the drug's risks exceeded its benefits. The court so found even though, pursuant to the Federal Food, Drug and

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[1] Pursuant to Supreme Court Rule 37.3(a), PLAC notes that all parties have consented to the filing of amicus briefs by letters of general consent filed with the Clerk. Pursuant to Supreme Court Rule 37.6, PLAC states that this brief was not authored, in whole or in part, by counsel for a party, and that no monetary contribution intended to fund the preparation or submission of this brief was made by any person or entity other than PLAC or its counsel.

[2] The corporate members of PLAC are listed in the Appendix to this brief.

[3] For example, PLAC submitted amicus briefs in *Wyeth v. Levine*, 555 U.S. 555 (2009), *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) and *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

Cosmetic Act ("FDCA"), the United States Food and Drug Administration ("FDA") had *approved* the drug for marketing in interstate commerce, finding the drug to be both "effective" and "safe," the latter because *the drug's benefits exceeded its risks*.

Because the FDCA forbids the marketing of new drugs unless they are approved by the FDA, and requires generic drugs to be the "same" in active ingredients and biological effect as the branded drug on which their approval is based, defendant would have been prohibited by the FDCA from changing its drug's design to meet New Hampshire law's requirements. The court of appeals rejected defendant's contention that this direct conflict with the FDCA preempted plaintiff's design defect claim, noting that defendant could lawfully have elected not to sell its drug in New Hampshire at all.

The court's radical conclusion is of great concern to PLAC members and their employees, shareholders and customers. Many PLAC members—which include manufacturers of branded and generic pharmaceuticals, medical and surgical devices, airplanes, automobiles, trucks, motorcycles, cigarettes and other tobacco products and alcoholic beverages, as well as oil and gas companies—are highly regulated by the federal government. Typically the applicable regulatory scheme involves a delicate balancing by an expert agency of the benefits of a product or activity against its costs and risks, and establishes federal requirements for selling or conducting the product or activity in interstate commerce. The notion that an individual state could *ban* a product or activity that is sold or conducted in a federally mandated fashion is contrary to prior decisions of this Court, would effectively eviscerate the

Supremacy Clause and would deprive consumers of innumerable beneficial products and services.

Moreover, the FDCA, like all federal statutory schemes, is motivated by certain Congressional objectives, in this case both to ensure that beneficial prescription drugs are freely available to patients and their physicians, and to lower the cost of healthcare by promoting the availability of inexpensive generic drugs. The product ban effected by the court of appeals' decision would deprive PLAC members' employees of the particular drug at issue here, and also subject PLAC's members or their employees to higher healthcare costs, which are likely in part also to be borne by shareholders and customers. State law bans of products or services governed by other federal regulatory schemes would equally frustrate important federal purposes.

STATEMENT OF THE CASE

The judgment below arises out of side effects suffered by plaintiff Karen L. Bartlett from use of the prescription drug sulindac. Sulindac was manufactured by defendant Mutual Pharmaceutical Company, Inc. ("Mutual") and is the generic form of the branded drug Clinoril®.[4]

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[4] Chemically, sulindac is (Z)-5-fluoro-2-methyl-1-[[p-(methylsulfinyl)phenyl]methylene]-1H-indene-3-acetic acid. FDA, *Clinoril Labeling Revision* (Dec. 23, 2010) at 1, http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/017911s074lbl.pdf.

Prior to 1978, pursuant to the FDCA, Clinoril's sponsor submitted a "New Drug Application" ("NDA") to the FDA for approval to market Clinoril in interstate commerce. The NDA was required to contain extensive information about the drug's composition and manufacture, results of all pre-clinical and clinical studies and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product . . . received by the applicant from any source." 21 C.F.R. § 314.50(d)(5)(iv); 21 U.S.C. § 355(b)(1)(A). The application was also required to include a specific "discussion of why *the benefits exceed the risks* under the conditions stated in the labeling." 21 C.F.R. § 314.50(d)(5)(viii) (emphasis added); *see also* 21 C.F.R. § 314.50(c)(2)(ix).

The FDA approved Clinoril's NDA in 1978. *Drugs@FDA Database – CLINORIL Approval History* (FDA), http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails. By that approval, the agency determined that the drug was "*safe* for use under the conditions prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. § 355(d) (emphasis added).

The FDA's conclusion that Clinoril was "safe" did not mean that it was 100% safe. To the contrary, "[n]o drug is absolutely safe; all drugs have side effects." *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (FDA) ("Review Process"), http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last visited January 5, 2013); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142 (2000) (noting that highly toxic drugs used in the treatment of various cancers are safe within the meaning of the FDCA "because,

for certain patients, the therapeutic benefits outweighs the risk of harm").[5]

Rather, by its safety determination the FDA concluded that the drug's *health benefits exceeded its risks*. 60 Fed. Reg. 39180 (1995) ("In evaluating . . . safety . . . FDA weighs the product's demonstrated effectiveness against its risks[,]. . . tak[ing] into account information such as the seriousness and outcome of the disease, the presence and adequacy of existing treatments, and adverse reaction and other safety data"); 71 Fed. Reg. 3934 (2006) ("the agency makes approval decisions based . . . on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling"); *United States v. Rutherford*, 442 U.S. 544, 555 (1979) (FDA considers drug safe when "expected therapeutic gain justifies the risk entailed by its use"); *Brown & Williamson*, 529 U.S. at 140 (same, citing *Rutherford*); *Review Process*, *supra* ("'Safe' in this sense means that the benefits of the drug appear to outweigh the known risks").

In 1987, pursuant to the Hatch-Waxman amendments to the FDCA, Mutual submitted an abbreviated NDA ("ANDA") to market sulindac as a generic form of Clinoril. *Drugs@FDA Approval History of Mutual's 200 mg sulindac* (FDA) ("Mutual Approval History"), http://www.accessdata.fda.gov/

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[5] By definition, a prescription drug, due to its "toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for use *except* under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A) (emphasis added).

scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails. The ANDA was required to demonstrate that sulindac was the "same as" Clinoril in active ingredients, route of administration, dosage form, strength and conditions of use recommended in the label, 21 U.S.C. § 355(j)(2)(A), and by appropriate testing that sulindac was bio- and therapeutically equivalent to Clinoril, *id.* In 1991, FDA approved Mutual's ANDA. *Mutual Approval History*, *supra*.

Following Clinoril's and sulindac's respective approvals, their manufacturers were required to report to FDA all adverse events associated with the drugs' use, 21 C.F.R. § 314.80, and periodically submit any new information that might affect FDA's previous conclusions about the drugs' safety, effectiveness or labeling, 21 C.F.R. § 314.81. *See also* 21 U.S.C. § 355(k); Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, § 901, 121 Stat. 922 (enhancing FDA authority to require post-market clinical trials and surveillance). Although FDA is required to withdraw a drug's approval if it finds that "clinical or other experience, tests, or other scientific data show that such drug is unsafe for use," 21 U.S.C. § 355(e); *see also Brown & Williamson Tobacco Corp.*, 529 U.S. at 134, FDA had commenced no such proceeding for Clinoril or sulindac as of the time plaintiff was prescribed the drug in 2004, *see CLINORIL Approval History, supra; Mutual Approval History, supra.*[6]

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[6] Over time, FDA has approved many NSAIDs, including Motrin, Naprosyn, Celebrex, Toradol, Daypro and Relafen. *Clinoril® Medication Guide* at 2-3. As the agency has done this, it has not generally withdrawn approval for prior NSAIDs, as patients respond differently to different compounds and FDA believes patients should have a choice of therapies. However, if

At that time, sulindac was indicated by its FDA-approved label (under the FDCA, the "same" as Clinoril's label) for acute or long-term use in treating osteoarthritis, rheumatoid arthritis, acute gouty arthritis, ankylosing spondylitis and acute painful shoulder (acute subacromial bursitis/supraspinatus tendinitis). *Clinoril Labeling Revision, supra.* Physicians were, however, free to prescribe the drug for "off-label" uses in the exercise of their clinical judgment. *E.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 & n.5 (2001) (noting "off-label" use of prescription drugs and devices is lawful under FDCA and widely accepted).[7]

Plaintiff's physician prescribed sulindac to treat her shoulder pain. *Bartlett v. Mut. Pharm. Co.*, 760 F. Supp. 2d 220, 228 (D.N.H. 2011) As a result,

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significantly safer NSAIDs become available, FDA may require a heightened benefit to justify marketing: for example, the agency expressed the view in 2005 that Bextra should be withdrawn because it presented greater risks than other NSAIDs with comparable efficacy, and the manufacturer withdrew it. See *Alert for Healthcare Professionals, Valdecoxib (marketed as Bextra)* (FDA April 7, 2005), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124649.htm.

[7] Sulindac is one of many drugs classified as non-steroidal anti-inflammatory drugs ("NSAIDs"). *See* FDA, *Clinoril® (Sulindac) Medication Guide* (July 2010) at 1, http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088573.pdf. Due to the prevalence of the painful conditions that these drugs treat, they are widely prescribed. Daniel H. Soloman, MD, MPH, "Nonselective NSAIDs: Overview of Adverse Effects," http://www.uptodate.com/contents/nonselective-nsaids-overview-of-adverse-effects (last visited on January 5, 2013) ("this class of drugs [is] one of the most commonly used in the world").

she suffered a severe dermatological side effect diagnosed as toxic epidermal necrolysis ("TEN") or Stevens-Johnson syndrome ("SJS").[8]

At trial, the jury found for plaintiff on her claim that sulindac was defectively designed. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 44 (1st Cir. 2012). The verdict was premised on plaintiff's claim, and the jury's finding, that the drug was unreasonably dangerous because its risks, particularly of TEN/SJS, outweighed its benefits. *Id.* at 34-35.

On appeal, the First Circuit rejected Mutual's argument that plaintiff's design defect claim was preempted by the FDCA. The court concluded that this Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), established a general no-preemption rule under the FDCA that applied to design defect claims involving prescription drugs as well as the failure-to-warn claims at issue in that case. *Bartlett*, 678 F.3d at 38. The court also concluded that this Court's holding in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), that failure-to-warn claims involving generic drugs *were* preempted by the FDCA because the act required such drugs to use the "same" labeling as their branded equivalents, carved out a limited ex-

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[8] TEN/SJS is a serious and potentially fatal condition characterized by necrosis of the skin and mucous membranes. *See Dorland's Illustrated Medical Dictionary* 1872 (31st ed. 2007). TEN is diagnosed when 30 percent or more of the outer skin layer on a patient's total body surface area has deteriorated, been burned off or turned into an open wound. *Bartlett*, 678 F.3d at 34. The risk of TEN/SJS was described in sulindac's labeling at the time Ms. Bartlett was prescribed the drug. *Bartlett*, 760 F. Supp. 2d at 229 (noting that "sulindac's label expressly mentioned SJS/TEN in its list of potential adverse reactions").

ception to *Levine* that did not extend to design defect claims. *Id.* at 38. Although the court acknowledged that the FDCA prohibited Mutual from altering the design of its drug, the court concluded that Mutual could have avoided a conflict between federal and state law by choosing not to sell sulindac at all. *Id.* at 37.

SUMMARY OF THE ARGUMENT

Under the Supremacy Clause of art. VI, sec. 2 of the United States Constitution, a federal statute preempts state law where either compliance with both federal and state law is impossible, or where state law stands as an obstacle to accomplishing the full purposes and objectives of the federal statute. Plaintiff's design defect claim was preempted under *both* standards.

First, plaintiff's claim was preempted because it was impossible for Mutual to comply with both the FDCA and New Hampshire product liability law. New Hampshire law held sulindac's design to be defective, and thus required Mutual to change the design. Had Mutual done that, however, it would have violated the FDCA in two respects. The altered product would have been a new drug under the statute, so that Mutual could not lawfully have sold the drug because it lacked an approved NDA to do so. Moreover, as the manufacturer of a generic drug, Mutual could not lawfully change sulindac's design to differ from that of Clinoril, the branded drug on which sulindac's ANDA was based. Because Mutual thus could not "independently do under federal law what state law requires," plaintiff's claim was preempted under the standard set forth by this Court in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579 (2011).

The court of appeals suggested *Mensing* was not controlling because it applied only to generic drug failure-to-warn, not design defect, claims, and that otherwise this Court had established a broad rule against the preemption of pharmaceutical product liability claims in *Wyeth v. Levine*, 555 U.S. 555 (2009). *Wyeth* did no such thing, however; to the contrary, as the Court made clear by citing *Wyeth* for the very standard the Court used to decide *Mensing*, both cases were resolved by applying precisely the same preemption principles.

The court further suggested that, even though the FDCA forbade Mutual to change sulindac's design, there was no conflict between the statute and state law because Mutual could simply have elected not to sell the drug in New Hampshire at all. This Court, however, has never held, or even suggested, that there is no actual conflict between federal and state requirements concerning a product if its supplier may lawfully forebear from selling it. If this argument were valid, the Court would not have found preemption in various product-related cases in which it has previously done so, including both "impossibility" and express preemption cases. In any event, the Court in *Mensing* rejected an argument to avoid preemption that could "often" be made in conflict preemption cases, because "[w]e do not read the Supremacy Clause to permit an approach to preemption that renders conflict preemption all but meaningless." 131 S. Ct. at 2579. *A fortiori*, therefore, the court of appeals' argument is invalid, as it would apply in literally every case where federal law establishes requirements for a product and thus render the Supremacy Clause *entirely* meaningless.

Second, plaintiff's claim was preempted because New Hampshire's prohibition of the sale of

sulindac would stand as an obstacle to the accomplishment of *two* core FDCA objectives. One important FDCA objective is to assure that drugs that are "safe" and "effective" are made available (as promptly as possible) to patients and their physicians, and the FDA's finding that a drug is "safe" means it is a *net benefit to public health* because its therapeutic benefits exceed its risks. A second FDCA objective, at least since the 1984 Hatch-Waxman Amendments, is to lower the cost of health care by making less-expensive generic drugs available to compete with branded drugs.

The judgment below, however, would frustrate accomplishment of both objectives. Under the judgment, New Hampshire patients and physicians would not only be deprived of a drug that provides a net health benefit, thus *harming* public health, they would be deprived of such a drug that is low in cost. Plaintiff's state law claim is thus preempted under the Court's well-established "obstacle" preemption jurisprudence, including *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (preempting state law claim of fraud by not providing FDA with information purportedly required by FDCA, as this would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives").

Indeed, permitting a jury to ban a prescription drug by a risk-benefit finding that is directly contrary to that made by the FDA is an even starker conflict with federal law than in *Buckman*. Such a result is particularly inappropriate because the agency employs expert professionals to make the assessment based on all available scientific information about the drug's benefits and risks, while the jury is comprised of lay persons, hears only the evidence

counsel selects and focuses solely on the particular patient and adverse event at issue.

ARGUMENT

I. PLAINTIFF'S DESIGN DEFECT CLAIM CONFLICTS WITH THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND HENCE IS PREEMPTED

The Supremacy Clause of art. VI, sec. 2 of the United States Constitution provides that the "Constitution and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the Supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." As this Court has held, "under the Supremacy Clause, from which our pre-emption doctrine is derived, 'any state law, however clearly within a State's acknowledged power, which *interferes with or is contrary to* federal law, must yield.'" *Gade v. National Solid Waste Management Association*, 505 U.S. 88, 108 (1992) (citations omitted) (emphasis added).

When a federal statute is involved, preemption of conflicting state law "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Gade*, 505 U.S. at 98 (citations omitted). State law conflicts where either "compliance with both federal and state [law] is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full pur-

poses and objectives of Congress." *Id.* [9] Here, plaintiff's design defect claim is preempted under *both* standards.

A. It Was Impossible for Mutual to Comply with Both the FDCA and New Hampshire Product Liability Law Regarding Sulindac's Design

1. New Hampshire Law Required Mutual to Alter Sulindac's Design, While the FDCA Forbade That

Plaintiff's claim was preempted because it was impossible for Mutual to comply with both the FDCA and New Hampshire product liability law regarding sulindac's design. As this Court held in *Mensing*, the test for "impossibility" preemption "is whether the private party could independently do under federal law what state law requires of it." 131 S. Ct. at 2579. Here Mutual could *not*.

Under the jury's verdict, sulindac was defectively designed, so Mutual could not lawfully sell the drug without changing its design. Were Mutual to

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[9] This Court has suggested that there may be a presumption against preemption at least in certain circumstances, but any such presumption "is *not* triggered when the State regulates in an area where there has been a history of significant federal presence." *United States v. Locke*, 529 U.S. 89, 108 (2000) (emphasis added). Pharmaceutical safety is precisely such an area, as federal regulation has been ongoing since 1848. Ch. 70, 9 Stat. 237 (1848); *see Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 704-705 (D.C. Cir. 2007), *cert. denied* 128 S. Ct. 1069 (Jan. 14, 2008).

have done that, however, sale of the drug would have been unlawful under the FDCA in two separate respects.

First, had Mutual altered sulindac's design, the product would have been a new drug under the FDCA. 21 U.S.C. § 321(p)(1) (defining new drug to be any drug "the composition of which . . . is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof"); 21 C.F.R. § 310.3(h) (giving examples where FDA considers drug to be new, including because of "newness for drug use of any substance which composes such drug, in whole or in part"); *see Sprague v. Upjohn Co.*, 1995 WL 376934, at *2 (D. Mass. May 10, 1994) ("Halcion is a prescription drug, for which the only active . . . ingredient is the chemical compound [t]riazolam. . . . To alter the chemistry of the [t]riazolam molecule, would be to create a new compound."). Under those circumstances, Mutual could not lawfully have sold the drug, as it would have lacked an approved NDA to do so. 21 U.S.C. § 355(a) (unlawful to sell new drug without approved NDA).

Second, as the manufacturer of a generic drug, Mutual could not lawfully change sulindac's design so as to differ from that of the branded drug, Clinoril, on which sulindac's ANDA was based. To the contrary, the FDCA expressly requires that a generic drug be compositionally the "same as" the predicate branded drug in "active ingredients," and functionally "bioequivalent to" it. 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.127(a)(3) (dissimilar "active ingredients" will cause rejection of applica-

tion for approval of generic drugs); 21 C.F.R. § 314.127(a)(7).

For these reasons, plaintiff's design defect claim was preempted by the FDCA. Indeed, this conclusion is directly compelled by this Court's rationale in *Mensing*. In that case, plaintiffs had developed tardive dyskinesia after taking generic metoclopramide, and brought failure-to-warn claims under state law alleging that manufacturers of the generic drugs should have employed stronger warnings. *Mensing*, 131 S. Ct. at 2573. Defendants argued the claims were preempted by the FDCA's requirement that generic drugs' labeling be the "same" as that of the predicate branded drug. *Id.* In response, plaintiffs argued defendants could have (i) utilized FDA's "changes-being effected" ("CBE") regulations to unilaterally strengthen their warnings while simultaneously seeking FDA approval of the strengthening, (ii) used "Dear Doctor" letters to send additional warnings to healthcare professionals or (iii) at least asked FDA to require the branded manufacturer to strengthen *its* warnings, allowing (indeed requiring) defendant to follow suit. *Id.* at 2575-2578.

Analyzing the relevant statutory and regulatory language (including FDA's own interpretations), however, the Court held that the first two options were forbidden by the FDCA, under which all labeling of a generic drug, including the content of any "Dear Doctor" letter, must be "the same *at all times* as the corresponding brand-name drug labels," *i.e.*, there was "an ongoing federal duty of 'sameness.'" *Id.* at 2575, 2577-2578 (emphasis added).

As to the third option, the Court held the option would not allow defendant to "*independently* do

under federal law what state law requires," which was required to avoid preemption. *Id.* at 2579 (emphasis added). While seeking FDA assistance *might* eventually result in a stronger warning, allowing such a mere possibility to avoid preemption "would make most conflicts between state and federal law illusory[,]" because "[w]e can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it." *Id.* "If these conjectures suffice to prevent federal and state law from conflicting . . . , it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. We do *not* read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless." *Id.* (emphasis added).

In short, because under the FDCA the defendant in *Mensing* could not independently have changed its warnings to satisfy its state law duty, plaintiff's claim was preempted. *Id.* at 2577-2578. In the present case, for the *two* FDCA reasons noted above, defendant Mutual could not lawfully have changed sulindac's design, a fact that the court of appeals itself acknowledged. *Bartlett*, 678 F.3d at 37 ("Mutual cannot legally make sulindac in another composition"). Having made this acknowledgment, the court erred in failing to hold plaintiff's claims preempted.[10]

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[10] Other courts have correctly followed *Mensing* to hold design defect claims against generic pharmaceutical manufacturers to be preempted. *E.g., Bartoli v. APP Pharms., Inc. (In re Pamidronate Prods. Liab. Litig.)*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012) ("the federal duty of 'sameness'" also applies in the context of generic drug design, and federal law preempts

state laws imposing a duty to change a drug's design on generic drug manufacturers"); *Frazier v. MYLAN Inc.*, 2012 U.S. Dist. LEXIS 183187, at *16-*19 (N.D. Ga. Dec. 18, 2012) (rejecting *Bartlett* and holding design defect claims preempted because "Mylan was not free to unilaterally pursue a safer alternative design of phenytoin to comply with state law while also being in compliance with federal law"); *Johnson v. Teva Pharms. USA, Inc.*, 2012 U.S. Dist. LEXIS 71384, at *12-*13 (W.D. La. May 21, 2012) (design defect claims preempted under *Mensing* because plaintiff "cannot show that an alternative drug design was available to the Generic Defendants"); *Lashley v. Pfizer, Inc.*, 2012 U.S. Dist. LEXIS 144060, at *6 (S.D. Miss. Oct. 1, 2012) (denying reconsideration of preemption of plaintiff's design defect claim because *Bartlett* "unpersuasive and not a proper basis for relief"); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 2011 U.S. Dist. LEXIS 135006, at *32 (D.N.J. Nov. 21, 2011) (applying *Mensing* to preempt defective design claim "because FDA requires generic Fosomax to have the same active ingredient as Fosamax"). Outside the pharmaceutical context, other "impossibility" preemption decisions of this Court also demonstrate the court of appeals' error in this case. *See, e.g., McDermott v. Wisconsin*, 228 U.S. 115, 133-134 (1913) (state law claim requiring food vendor to use state-specific label preempted because would cause product to be misbranded under federal Pure Food and Drug Act of 1906); *Hisquierdo v. Hisquierdo*, 439 U.S. 572, 590 (1979) (state community property law that expressly divided railroad retirement income in the case of divorce preempted because federal Railroad Retirement Act prohibited assignment of railroad retirement income); *Am. Tel. & Tel. Co. v. Centraloffice Tel.*, 524 U.S. 214 (1998) (state law breach of contract claims for failing to provide service options not in federally filed tariff preempted because claims "directly conflict" with Federal Communications Act limiting contract to terms of tariff).

2. If Accepted, the Court of Appeals' "Forebear from Selling" Argument Would Render the Supremacy Clause Meaningless

The court of appeals' initial justification for avoiding *Mensing*'s rationale was to assert that *Wyeth* established a broad no-preemption rule for pharmaceutical product liability claims, while *Mensing* established only a narrow exception for generic drug failure-to-warn claims into which this case did not fall. *Bartlett*, 678 F.3d at 37. But *Wyeth* established no such sweeping "rule"; rather, it applied to its facts precisely the same well-established "impossibility" preemption principles that the Court later applied in *Mensing*. *Wyeth*, 129 S. Ct. at 568-573.

Indeed, in *Mensing* the Court made explicit that it was applying the same standard in both cases, as the Court cited *Wyeth* itself for the governing principle that "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." 131 S. Ct. at 2579 (citing "*Wyeth*, 555 U.S. at 573"). The only reason for *Wyeth*'s no-preemption holding was that the FDA's CBE regulations *allowed* the branded manufacturer in that case unilaterally to strengthen its warnings (so long as it simultaneously applied for FDA approval) as required by state law. *Wyeth*, 129 S. Ct. at 1196-99 (citing 21 C.F.R. § 314.70(c)(6)(iii)(A), 21 C.F.R. § 314.70(c)(6)(iii)(C) (2004)). That holding is inapplicable here where the

relevant FDCA provisions and regulations forbade defendant unilaterally to change its drug's design.[11]

The court of appeals' ultimate rationale for finding no preemption in this case, however, was that there was simply no federal-state law conflict because "the decision to make the drug and market it in New Hampshire is wholly [Mutual's]," and Mutual "can choose not to make [or sell in New Hampshire] the drug at all." *Bartlett*, 678 F.3d at 37-38.[12] Certainly, this Court has never held—nor,

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[11] The Court in *Wyeth* foreshadowed how it would resolve the preemption issue in a pharmaceutical product liability case in which the defendant could *not* do under the FDCA what state product liability law required, noting that if there was "clear evidence" FDA would not have approved labeling changes required by state law, the Court *would* "conclude that it was impossible for [defendant] to comply with both federal and state requirements," *i.e.*, find preemption. 129 S. Ct. at 1198. Even before *Mensing*, therefore, lower courts had applied *Wyeth* to reach precisely this result when presented with a proper record. *E.g., Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010) (preempting claims that manufacturer should have adopted stronger warning: "The FDA decided not to require such a warning because it would confuse rather than inform; and a court cannot order a drug company to place on a label a warning if there is 'clear evidence' that the FDA would not approve it") (citing *Wyeth*); *Dobbs v. Wyeth Pharms.*, 797 F. Supp. 2d 1264, 1277 (W.D. Okla. 2011) (finding impossibility preemption of failure-to-warn claim based on clear evidence FDA would have rejected enhanced suicide warning).

[12] At some literal or theoretical level, such a course of action would not conflict with federal law because the FDCA does not affirmatively *require* Mutual to make sulindac or sell it in New Hampshire, so it would not be "impossible" for Mutual to comply with both federal and state law. But by prescribing the requirements for the sale of any drug in interstate commerce, the FDCA necessarily assumes that the drug *will*

to amicus' knowledge, has the Court even *suggested*—that there is not an actual conflict between federal and state requirements concerning a product if its supplier may lawfully forebear from selling it.

Moreover, if this obvious and literalist argument were valid, the Court would not have found "impossibility" preemption in any of the product-related cases in which the Court *has* found such preemption. *E.g., McDermott v. Wisconsin*, 228 U.S. 115, 133-134 (1913) (where state law required labeling of maple syrup in manner that federal law prohibited, retail merchants could not comply with both federal and state law and hence state law was preempted); *Mensing*, 131 S. Ct. at 2577 (where state product liability law required warnings for generic drug which federal law prohibited, manufacturer could not comply with both federal and state law and hence state law claim was preempted).

Indeed, if accepted, the argument would also reverse the holdings of various *express* preemption cases involving products that are subject to federal requirements. *See, e.g., Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-524 (1992) (state law claim requiring additional health warnings on cigarette packages preempted by Federal Cigarette Labeling and Advertising Act imposing federal warning requirements and expressly preempting any state law "requirement or prohibition based on smoking and

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indeed be so sold; moreover, this is so with respect to any other product or activity the sale or conduct of which is subject to federal requirements. In any event, as discussed in the text, this Court has made clear that such a sweeping literalist argument cannot be permitted effectively to nullify the Supremacy Clause.

health . . . with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act"); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008) (state law negligence and strict liability claims preempted by FDCA's Medical Device Amendments imposing requirements on approved medical devices and expressly preempting states from imposing "any requirement . . . different from, or in addition to any requirement under [FDCA]").

In any event, the invalidity of the "forebear from sale" argument under the Supremacy Clause follows *a fortiori* from *Mensing*. There the Court held that the argument that defendant *might* ultimately be able with government or third-party assistance to accomplish lawfully under federal law what state law required did not defeat preemption. As the Court noted, such an argument could "often" be made in conflict preemption cases, and "[w]e do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless." 131 S. Ct. at 2579.

In contrast to the "possibility" argument, the "forebear from sale" argument adopted by the court of appeals would avoid preemption in literally *every* case involving conflicting federal and state requirements concerning the sale of a product, or the conduct of other activities, in commerce. The argument would thus render conflict preemption not merely "all but meaningless," but entirely so. The lower court's acceptance of the argument was error.[13]

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[13] Various other courts have so realized. *E.g., In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, 2012 WL 718618, at *3 (E.D. Ky. March 5, 2011) ("[T]he

B. New Hampshire's Prohibition of the Sale of Sulindac Frustrated Two FDCA Objectives—Making Beneficial Drugs Available to Patients and Their Physicians, and Lowering the Cost of Prescription Drugs

If for some reason—contrary to the arguments set forth above—the Court were to find no "impossibility" preemption because Mutual could have cho-

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idea that [the manufacturer] should have simply stopped selling [the drug] is an oversimplified solution that could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether."); *Jacobsen v. Wyeth*, LLC, 2012 U.S. Dist. LEXIS 116887, at *33 (E.D. La. Aug. 20, 2012) ("If state law could require a generic drug manufacturer to wholly withdraw from the market based on the unreasonable danger of the product (which is all a successful failure to withdraw from the market claim could be), it necessarily must repudiate the label approved by the FDA.")(citation omitted); *Aucoin v. Amneal Pharms., LLC*, CCH Prod. Liab. Rep. P18,891, at *30 (E.D. La. July 20, 2012) (same); *Eckhardt v. Qualitest Pharms., Inc.*, 858 F. Supp. 2d 792, 801 (S.D. Tex. 2012) ("a state law requirement that the drug be completely withdrawn from the market, based solely on a theory that the federally mandated label was inadequate, would also impermissibly conflict with federal law and be preempted"); *In re Fosamax*, 2011 U.S. Dist. LEXIS 135006 at *36 n.5 (D.N.J. Nov. 21, 2011) ("To accept Plaintiffs' argument that Generic Defendants could have simply stopped marketing alendronate sodium, this Court would have to directly contravene binding law."); *Coney v. Mylan Pharms. Inc.*, CCH Prod. Liab. Rep. P18,778, at *12-*13 (S.D. Ga. Jan. 19, 2012) (rejecting argument that Mylan could have simply chosen to take phenytoin off the market because "[f]inding that state law prohibits Mylan from doing what federal law explicitly requires Mylan to do would be tantamount to conferring supremacy upon the state law").

sen not to sell sulindac in New Hampshire, the Court would still be required to find "obstacle" preemption. Under these circumstances, New Hampshire's prohibition of the sale of sulindac would stand as an obstacle to the accomplishment of *two* core Congressional objectives under the FDCA—ensuring that beneficial drugs are available to patients and their physicians, and lowering the cost of prescription drugs.

One primary statutory objective of the FDCA is to assure that safe and effective drugs are made available to patients and their physicians, and indeed that this occurs *promptly*. Hence the statute commands that the FDA "shall" approve an NDA or ANDA within 180 days unless the agency finds the drug has not been shown to meet the statutory conditions for approval, including safety and efficacy for a new drug or sameness for a generic one. 21 U.S.C. § 355(c)(1) (NDA), 21 U.S.C. § 355(j)(5)(a) (ANDA); *see also* 21 U.S.C. § 393(b)(1) (commanding FDA to "promptly and efficiently review[] clinical research and tak[e] appropriate action on the marketing of regulated products in a timely manner").

Moreover, as noted earlier, the FDA's finding that a drug has been shown to be "safe" means that the drug is a *net benefit to public health*, *i.e.*, that its benefits in the form of disease prevention, cure or mitigation exceed its risks in the form of adverse effects. 60 Fed. Reg. 39180; 71 Fed. Reg. 3934; *Rutherford,* 442 U.S. at 555; *Brown & Williamson*, 529 U.S. at 140, 142.[14]

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[14] Congress has explicitly recognized that the FDA's role in approving drugs for sale in commerce is a matter of "public health." *See, e.g.*, 21 U.S.C. § 393(b)(2)(B) (defining

In addition, and as this Court has already recognized, a second core objective of the FDCA, at least since enactment of the 1984 Hatch-Waxman Amendments,[15] is to lower the cost of health care by making less-expensive generic drugs available to compete with branded drugs. H.R. Rep. No. 98-857, pt. 1, p. 14 (1984) (describing amendments' purpose as to "make available more low cost generic drugs by establishing a generic drug approval procedure"); *Mensing*, 131 S. Ct. at 2574, 2582 (noting that ANDA process "allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug," and hence "allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public").[16]

In the present case, the judgment below—to the effect that generic sulindac cannot lawfully be

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FDA's mission as, in part, to "protect the public health by ensuring that . . . drugs are safe and effective"), 21 U.S.C. § 393(b)(1) (commanding FDA to "promote the public health" by taking prompt action on drug marketing).

[15] The amendments are more formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

[16] Other courts, including the court of appeals itself, have recognized this essential Congressional purpose. *Accord In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (purpose of Hatch-Waxman Amendments is "to get generic drugs into the hands of patients at reasonable prices—fast"); *Bartlett*, 678 F.3d at 37 ("There is no doubt that Congress wanted to reduce medical costs by spurring generic copycat drugs, and accordingly generic manufacturers do not, after patent protection lapses, need separate FDA approval to manufacture approved drugs or employ their approved label.").

sold in New Hampshire because the drug is unreasonably dangerous in design—interferes with the accomplishment of *both* of these core FDCA objectives. That is, by this judgment New Hampshire patients and physicians are not only deprived of a drug the FDA has found to be safe and effective, they are deprived of such a drug that is low in cost.

For these dual reasons, therefore, plaintiff's state law claim conflicts with the FDCA and is impliedly preempted. *See, e.g., Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 879, 881 (2000) (state law design defect claim mandating use of airbag in automobile impliedly preempted by National Traffic and Motor Vehicle Safety Act, as claim was obstacle to purpose of regulations under statute which deliberately permitted marketplace to experiment with different passive restraint devices because "a mix of devices would help develop data on comparative effectiveness, would allow the industry time to overcome the safety problems and the high production costs associated with airbags, and would facilitate the development of alternative, cheaper, and safer passive restraint systems"); *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494-497 (1987) (state law nuisance claim regarding interstate pollution impliedly preempted by Clean Water Act because would "upset the balance of public and private interests so carefully addressed" by the statute); *Perez v. Campbell*, 402 U.S. 637, 653 (1971) (state law suspending drivers' licenses of individuals who failed to pay judgments arising from automobile accidents preempted as obstacle to federal bankruptcy statute's mandate of establishing uniform national standards for discharge of debts); *Nash v. Florida Industrial Commission*, 389 U.S. 235, 239-240 (1967) ("coercive" state law denying unemployment benefits

to individuals filing unfair labor practice charges with National Labor Relations Board preempted by National Labor Relations Act because law "frustrat[ed] the purpose of Congress to leave people free to make charges of unfair labor practices" under the statute).[17]

Indeed, the conflict with federal objectives here is similar to, but considerably more acute than, the conflict that led this Court to find implied preemption in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). There plaintiff sought to recover on a state law claim that defendant had committed fraud on the FDA—by withholding information about a medical device's actual intended uses—in seeking clearance to market the device as "substantially equivalent" to already marketed devices. *Id.* at 346-347. The Court noted that under the medical device provisions of the FDCA, "the FDA pursues difficult (and often competing) objectives," *id.* at 349, including ensuring that devices are "reasonably safe and effective," getting them "on the market within a relatively short period" and making

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[17] Notably, this is not a case where federal law sets only a "minimum" standard for protecting public health, so that a "higher" standard under state law arguably would not frustrate the federal objectives. Rather, federal law has set an *optimal* standard, namely, that sulindac should be available because it provides a net public health benefit (and a low-cost one), so that a state law ban would create a public health *detriment* (and eliminate the low-cost product), achieving the precise opposite of the federal objectives. In addition, frustration of the federal objectives could not be avoided, even in a theoretical and literalist fashion, by Mutual's forbearing from selling sulindac. Rather, such forbearance would be directly to the contrary of the federal objectives of assuring the availability of beneficial, and low-cost, drugs to patients and physicians.

them available to patients and physicians, including for "'off-label' usage," *id.* at 350. The agency had authority to punish and deter fraud on itself, and "this authority is used by the Agency to achieve a somewhat delicate balance of [these] statutory objectives." *Id.* at 348.

Under these circumstances, the Court held that the state law claim would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives." *Id.* at 350. For example, permitting such claims "may" deter manufacturers from applying for approval of beneficial new devices, which "could" deprive patients of those devices both for approvable purposes as well as generally accepted off-label uses. *Id.* at 350-351. Alternatively, permitting the claims might cause applicants to include a deluge of information in applications, which in turn "could" cause delays in getting devices to market, thus "delay[ing] health care professionals' ability to prescribe appropriate off-label uses." *Id.* at 351.

In the present case, the FDA similarly engages in a "somewhat delicate balance of statutory objectives," *id.* at 348, including balancing risks against benefits in approving a drug for marketing. In so doing, the agency expressly found that sulindac as designed provides a net public benefit, because its benefits exceed its risks, so the drug *should* be available to patients and their physicians. The contrary New Hampshire rule not merely "may" or "could" achieve contrary results, *id.* at 350-351, it would indisputably do so, and the rule would not merely "*delay* health care professionals' ability to prescribe," *id.* at 351 (emphasis added), but definitively eliminate it.

Finally, permitting a lay jury applying state law to ban a prescription drug FDA has determined to be a public health benefit is *particularly* inappropriate given the disparate information and expertise available to the respective decision-makers. In approving Clinoril and then sulindac, the FDA had the benefit of a comprehensive NDA containing preclinical and clinical studies as well as all other available data relating to safety and effectiveness, 21 C.F.R. § 314.50, extensive post-marketing reports, 21 C.F.R. § 314.80(c)(2), 21 C.F.R. § 314.81(b)(2)(i), neutral outside expert advisory committees, 21 C.F.R. § 14.171, plus internal physician and scientist reviewers, and made a *prospective* determination of the benefit-risk ratio considering *all* potential users of the drug.

By contrast, and as this Court has noted in the similar context of medical device preemption, a jury making a risk-benefit decision in a tort lawsuit hears only the small subset of the available data that counsel elect to place before it, typically focuses only on the particular risk at issue in the case, generally has no expert members, hears only from partisan experts hired by the parties and decides the issue only in retrospect and in the context of a single patient who has suffered a particular side effect.[18] *See Riegel*, 552 U.S. at 324-326 (finding claims against medical device manufacturer expressly preempted; permitting claims would "disrupt the [FDCA's] regulatory scheme" because a jury inevitably focuses on risk to injured plaintiff and "is not concerned with [product's] benefits," while FDA's

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[18] In this case, for example, the evidence focused almost exclusively on the risk of TEN/SJS.

risk-benefit determination considers interests of *all* potential users, including "those who would suffer *without* [the product]") (emphasis added).[19]

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[19] For all the above reasons, the lower courts have held state-law attempts to regulate the availability of prescription or over-the-counter drugs, and indeed to countermand the risk-benefit decisions of other federal agencies, to be impliedly preempted. *E.g., Autin v. Solvay Pharms., Inc.*, 05-2213, 2006 U.S. Dist. LEXIS 19507, at *11 (W.D. Tenn. Mar. 31, 2006) (negligence, warranty and other state law claims for selling non-FDA-approved drug without affirmative FDA finding drug was "generally recognized as safe and effective"—which, under FDCA, drug must be to be sold without approval—preempted because "court cannot usurp the FDA's power to evaluate the effectiveness of a drug or to approve a drug"); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011), *reconsideration denied*, 825 F. Supp.2d 661 (D. Md. 2012) (state law duty compelling generic manufacturers to stop production of drug that under federal law they have authority to produce "would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce"); *Robinson*, 651 F.3d at 869 (claims for selling over-the-counter drug without stronger warnings of prescription version preempted; "The decision whether to permit a drug to be sold over the counter rather than just by prescription is for the FDA. . The agency bases its decision on whether the drug is safe and effective for use without a doctor's permission . and it has decided not to require [that drug] be sold by prescription only."); *see also Farina v. Nokia, Inc.*, 625 F.3d 97, 126 (3d. Cir. 2010) (claims against cell phone manufacturers for injuries from radio frequency emissions preempted because in regulating emissions Federal Communications Commission weighs safety against efficiency and national uniformity; "[a]llowing juries to perform their own risk-utility analysis and second-guess the FCC's conclusion would disrupt the expert balancing underlying the federal scheme").

CONCLUSION

For all the foregoing reasons, amicus urges the Court to reverse the decision below.

Respectfully submitted,

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January 22, 2013

APPENDIX

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Corporate Members of the Product Liability Advisory Council as of 1/15/2013 ..... 1a

Corporate Members of the
Product Liability Advisory Council
as of 1/15/2013
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Altec, Inc.
Altria Client Services Inc.
Ansell Healthcare Products LLC
Astec Industries
Bayer Corporation
BIC Corporation
Biro Manufacturing Company, Inc.
BMW of North America, LLC
Boehringer Ingelheim Corporation
The Boeing Company
Bombardier Recreational Products, Inc.
BP America Inc.
Bridgestone Americas, Inc.
Brown-Forman Corporation
Caterpillar Inc.
CC Industries, Inc.
Chrysler Group LLC
Cirrus Design Corporation
Continental Tire the Americas LLC
Cooper Tire & Rubber Company
Crown Cork & Seal Company, Inc.
Crown Equipment Corporation
Daimler Trucks North America LLC
Deere & Company
The Dow Chemical Company

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Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, LLC
Exxon Mobil Corporation
FMC Corporation
Ford Motor Company
General Electric Company
General Motors LLC
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
Honda North America, Inc.
Hyundai Motor America
Illinois Tool Works Inc.
Isuzu North America Corporation
Jaguar Land Rover North America, LLC
Jarden Corporation
Johnson & Johnson
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Magna International Inc.
Marucci Sports, L.L.C.
Mazak Corporation

Mazda Motor of America, Inc.
Medtronic, Inc.
Merck & Co., Inc.
Meritor WABCO
Michelin North America, Inc.
Microsoft Corporation
Mine Safety Appliances Company
Mitsubishi Motors North America, Inc.
Mueller Water Products
Mutual Pharmaceutical Company, Inc.
Navistar, Inc.
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Novartis Pharmaceuticals Corporation
PACCAR Inc.
Panasonic Corporation of North America
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Polaris Industries, Inc.
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Purdue Pharma L.P.
RJ Reynolds Tobacco Company
Schindler Elevator Corporation
SCM Group USA Inc.
Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.
St. Jude Medical, Inc.
Stanley Black & Decker, Inc.

Subaru of America, Inc.
Techtronic Industries North America, Inc.
Teva Pharmaceuticals USA, Inc.
TK Holdings Inc.
The Toro Company
Toyota Motor Sales, USA, Inc.
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen Group of America, Inc.
Volvo Cars of North America, Inc.
Wal-Mart Stores, Inc.
Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.

AMICUS CURIAE BRIEF

Supreme Court, U.S.
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No. 12-142

IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioners,

v.

KAREN L. BARTLETT,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

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INTEREST OF AMICI

Amici are scholars and teachers in various fields of public law that bear on federal preemption of state law.[1] William Buzbee is Professor of Law at Emory University School of Law, where he teaches Environmental and Administrative Law and directs the Center on Federalism and Intersystemic Governance. Daniel Farber is the Sho Sato Professor of Law at the University of California, Berkeley School of Law, where he teaches Constitutional Law, Environmental Law, and Torts and co-directs the Center for Law, Energy and the Environment. Stephen Gardbaum is the MacArthur Foundation Professor of International Justice and Human Rights at the UCLA School of Law, where he teaches Constitutional Law, Comparative Law, and International Law. Garrick Pursley is Assistant Professor of Law at the Florida State University College of Law, where he teaches Federal Jurisdiction, Legislation/Regulation, and Constitutional Law. David Rubenstein is Associate Professor of Law at Washburn University School of Law, where he teaches Constitutional Law, Administrative Law, and Immigration Law. Ernest Young is the Alston & Bird Professor of Law at Duke Law School, where he teaches Constitutional Law and Federal Courts.

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[1] The parties' blanket consents to the filing of *amicus* briefs have been filed with the Clerk. No counsel for a party has written this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the *amici curiae* or their counsel, has made a monetary contribution to this brief's preparation or submission.

Amici have each written extensively on questions involving the preemption of state law by federal statutes and regulations. We submit this brief as an opportunity to bring our scholarship to bear on questions of public importance facing the Court.

SUMMARY OF ARGUMENT

This case raises three significant questions. The first is a general one concerning this Court's preemption doctrine: What showing is necessary to establish conflict preemption under a federal statutory regime that expressly preserves a role for state law? This is a crucial question for the balance of our federalism. Under contemporary interpretations of Congress's Article One powers, national regulatory authority is largely concurrent with that of the states, so that the boundary between federal power and state regulatory autonomy is largely defined by the scope and limits of federal preemption. For that reason, this Court has organized its jurisprudence around the "presumption against preemption" recognized in *Rice v. Santa Fe Elevator Co.*, 331 U.S. 218, 230 (1947). In cases of implied conflict preemption, that presumption both limits the scope of relevant purposes that may create a conflict with federal law and requires that such conflicts be serious before preemption is warranted. In this case, *Rice* requires rejection of both Petitioner's broad theory of impossibility preemption and its equally broad and open-ended argument for "purposes and objectives" preemption.

The second question concerns the role of state tort law under the federal regulatory regime governing prescription drugs. That regime explicitly preserves a role for state law. And, unlike the otherwise

parallel regime for medical devices, it does not feature an express preemption provision displacing state law "requirements" that diverge from federal law. This Court has thus construed state law as serving a complementary function to federal regulation of prescription drugs. *See Wyeth v. Levine*, 555 U.S. 555 (2009). State law provides compensation for persons injured by dangerous drugs—a function that federal law makes no effort to duplicate. And while federal regulation focuses on the premarket approval of prescription drugs, state tort law provides a mechanism and incentives for *ex post* review of those drugs after they enter the marketplace—a function that this Court has recognized the federal Food and Drug Administration is ill-equipped to carry out. *See id.* at 579 & n.11. Both Petitioners' impossibility and "purposes and objectives" arguments—which are variations on the same theme—would eliminate state law's complementary role by holding that federal approval provides not only permission but a *right* to market a drug free of any state law constraint. This Court should not presume, absent clear evidence to the contrary, that Congress intended this result.

The third question requires a careful analysis of *state* law, in order to determine whether that law actually conflicts with the federal regulatory regime. New Hampshire imposes strict liability—that is, liability without fault—on manufacturers of unreasonably dangerous products. The New Hampshire Supreme Court has made clear that this liability does not impose any duty other than to compensate persons injured by such products: there is, to use the language of express preemption clauses

in other statutes, no state law "requirement" that manufacturers alter their product (much less stop selling it). Petitioners dispute this reading of state law, but they primarily rely on *this Court*'s holdings, under various express preemption statutes inapplicable here, that state tort duties *always* impose "requirements" that manufacturers alter their products. Not only are those statutes inapplicable to this case, but this Court is bound, as always, by the state courts' construction of the duties imposed under state law. And in any event, even if state law *did* require Petitioners to stop selling their product in New Hampshire, the First Circuit correctly concluded that that obligation would not create a conflict sufficient to warrant preemption.

ARGUMENT

I. THIS COURT SHOULD REQUIRE EVIDENCE OF A SIGNIFICANT CONFLICT WITH CONGRESS'S CLEAR INTENT BEFORE FINDING PREEMPTION.

In assessing the scope of federal preemption, this Court has generally appreciated "the practical importance of preserving local independence, at retail, i.e., by applying pre-emption analysis with care, statute by statute, line by line, in order to determine how best to reconcile a federal statute's language and purpose with federalism's need to preserve state autonomy." *Egelhoff v. Egelhoff*, 532 U.S. 141, 160 (2001) (Breyer, J., dissenting). This Court's enumerated powers jurisprudence has generally given wide scope to Congress's regulatory authority, *see, e.g.*, *United States v. Comstock*, 130 S. Ct. 1949 (2010); *Gonzales v. Raich*, 545 U.S. 1 (2005), with the result that that authority is now, with certain important but relatively narrow exceptions,

largely concurrent with that of the states. Under these circumstances, it is particularly critical that the preemptive effect of federal legislation stretch no further than Congress clearly intended. *See* Ernest A. Young, *"The Ordinary Diet of the Law": The Presumption Against Preemption in the Roberts Court*, 2011 Sup. Ct. Rev. 253, 265-69; Stephen A. Gardbaum, *The Nature of Preemption*, 79 Cornell L. Rev. 767, 805-07 (1994). Hence, this Court has applied a "presumption against preemption" in construing the meaning of federal statutes and assessing potential conflicts between state and federal law. *See Rice*, 331 U.S. at 230.

Rice's presumption governs this case. In recent years, this Court has soundly rejected arguments for restricting *Rice*'s applicability, and it has recognized that *Rice* requires not only a clear statement of Congress's intent in express preemption cases but also a significant conflict in implied preemption cases. Critically, this Court insisted just two terms ago that "[o]ur precedents 'establish that a high threshold must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act.'" *Chamber of Commerce v. Whiting*, 131 S. Ct. 1968, 1985 (2011) (quoting *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 110 (1992) (Kennedy, J., concurring in part and in the judgment)). Petitioners' broad view of impossibility preemption would subvert this "high threshold" by finding such preemption whenever state law potentially forbids something that federal law permits. Worse still, Petitioners' open-ended arguments for "purposes and objectives" preemption would obviate the limits on impossibility preemption by permitting displacement of state law in an even

broader class of cases, limited only by courts' creativity in imputing purposes to Congress.

It is crucial to constrain preemption doctrine within narrower limits than those Petitioners propose. Contemporary federalism doctrine relies largely on two sets of institutional safeguards to preserve state autonomy: the representation of the States in Congress, and the procedural difficulty of enacting supreme federal law. *See* Bradford R. Clark, *Separation of Powers as a Safeguard of Federalism*, 79 Tex. L. Rev. 1321 (2001). In order to respect these safeguards, courts should find preemption based only on the text enacted by Congress and necessary implications from that text.

A. The presumption against preemption governs this case.

This Court has acknowledged "the historic primacy of state regulation of matters of health and safety," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), and accordingly applied a "presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation." *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 716 (1985). *Wyeth*, in particular, emphasized that "'[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" 555 U.S. at 565 (quoting *Medtronic*, 518 U.S. at 485, in turn quoting *Rice*). The defendants in *Wyeth* argued that *Rice* should not apply because of

the longstanding federal regulatory presence in the field of prescription drugs, but the Court specifically rejected this argument, noting that "[t]he presumption . . . accounts for the historic presence of state law but does not rely on the absence of federal regulation." *Id.* at 565 n.3

Wyeth likewise explicitly rejected an argument the *Rice* does not apply to claims of implied conflict preemption, stating that "this Court has long held to the contrary." *Id.* (citations omitted). It is worth re-emphasizing in this case, however, the implications of that holding. In express preemption cases, the *Rice* presumption operates as an aid for determining the meaning of ambiguous statutory text. It cannot play that same role when preemption rests not on the express language of the statute but rather on a conflict with federal requirements or purposes. Conflict preemption cases require an assessment not only of whether "federal law . . . is in tension with state law," but also "whether this tension is sufficiently severe to warrant the displacement of state law." Thomas W. Merrill, *Preemption and Institutional Choice*, 102 Nw. U. L. Rev. 727, 743 (2008) ; *see also* Young, 2011 Sup. Ct. Rev. at 274-76. As this Court noted in *Whiting*, the relevant precedents set a "high threshold" for conflict preemption. 131 S. Ct. at 1985.

In a conflict preemption scenario, the presumption against preemption operates in two distinct ways: It increases the *level* of conflict necessary to find preemption, and it narrows the range of federal purposes that may create a potential conflict with state law. The first of these dimensions governs Petitioners' impossibility argument, *see* Petitioner's Brief at 29-45, while both are relevant to

Petitioners' arguments for "purposes and objectives" preemption, *see id.* at 45-62.

B. Petitioners' theory of impossibility preemption is overbroad.

Impossibility preemption "is a demanding defense," *Wyeth*, 555 U.S. at 573, that requires defendants to demonstrate that "compliance with both federal and state [law] is a physical impossibility," *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963); *see also id.* at 143 (requiring proof of an "inevitable collision" between federal and state law). As we explain further in Part III, there is no serious argument in the present case that it is physically impossible to comply with state tort law. Federal law does not prohibit compensating persons injured by prescription drugs. Nor does it require manufacturers to continue or discontinue selling their drug upon a state law finding that the drug is defectively designed.

In this case, Petitioners appear to take the position that when a federal agency approves a drug for marketing, that approval operates as a license preempting any state-law duty that might discourage or prohibit such marketing. "Impossibility" occurs, on this view, when state law discourages action approved by federal regulators. That would be a radically broad reading of impossibility preemption, based on a fundamental misconception of the federal regime governing prescription drugs. That regime, as we elaborate in Part II, preserves state tort law as a complementary form of regulation to federal pre-market approval.

C. "Purposes and objectives" preemption should be construed narrowly.

To the extent that federal law may displace state law even when it is not impossible to comply with both, the *Rice* presumption speaks both to the severity of the conflict and the scope of relevant federal purposes. This Court has said that "the inquiry is whether there exists an irreconcilable conflict between the federal and state regulatory schemes. The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute." *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982); *see also English v. Gen. Elec. Co.*, 496 U.S. 72, 90 (1990) ("The "teaching of this Court's decisions . . . enjoins seeking out conflicts between state and federal regulation where none clearly exists.'" (quoting *Huron Cement Co. v. Detroit*, 362 U.S. 440, 446 (1960))). As Justice Kennedy has pointed out, "[a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law." *Gade*, 505 U.S. at 111 (Kennedy, J., concurring in part and in the judgment).

Virtually any federal statute may be construed to embody a range of potential purposes. The primary purpose of federal drug regulation is to protect public safety, but the FDCA regime also promotes competition in the drug market and seeks to reduce the compliance costs of drug manufacturers. It is not wholly implausible to see many FDA approvals as involving a balancing of these values, and from that perspective, *any* form of state regulation that might, say, increase costs to augment safety would be a movement away from the balance struck by federal

law. To take this view, however, would be to categorically exclude any form of supplemental state regulation; it would be, in other words, to make every federal floor a ceiling as well. *See generally* William W. Buzbee, *Asymmetrical Regulation: Risk, Preemption, and the Floor/Ceiling Distinction*, 82 N.Y.U. L. Rev. 1547 (2007). That conclusion is directly at odds with *Wyeth* and in tension with a long line of cases rejecting similar conclusions in other federal regulatory fields. *See, e.g.*, *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 450-51 (2005) (holding that state law suits can supplement federal requirements and rejecting complaints that such suits increase costs for manufacturers).

In order to avoid this categorical approach to implied conflict preemption, *Rice* requires a narrower focus on a statute's primary objective. As Justice Kennedy has observed, "this type of pre-emption should be limited to state laws which impose prohibitions or obligations which are in direct contradiction to Congress's primary objectives, as conveyed with clarity in the federal legislation." *Gade*, 505 U.S. at 110 (Kennedy, J., concurring in part and in the judgment). This approach, moreover, constrains judges from engaging in a "freewheeling" inquiry that risks imputing purposes that Congress did not contemplate. *See Bates*, 544 U.S. at 459 (Thomas, J., concurring in judgment in part and dissenting in part). In this case, for instance, a key question is whether Congress's purpose in creating a pre-marketing approval scheme administered by the FDA was simply to provide initial safety review before drugs go into public use, or instead to eliminate pre-existing state rights of action for

injured patients. *Rice* suggests the Court should adopt the narrower view of Congress's purpose.

Most legal regimes involve a tradeoff between conflicting purposes, and *Rice* can also speak to the degree to which state law may pursue a policy in tension with federal purposes. Here, for instance, one purpose of the Hatch-Waxman Act is to increase the availability of generic drugs, and Petitioners have argued that any state rule that tends to discourage the marketing of a generic drug or affects generic manufacturers' costs of doing business is therefore preempted. The question, however, is whether state law can pursue its purpose of ensuring compensation for injured consumers and providing back-end safety review even when that may impose some additional costs on generic drug manufacturers. *Rice* suggests that this sort of tension is tolerable; it also suggests, as we discuss further in Part II, that Congress's purpose should not be construed as promoting generic drugs *uber alles*, but rather as encouraging generic use so long as that is consistent with the states' traditional role of compensating injured patients and supplementing federal safety review.

D. Doctrines limiting federal preemption of state law play a critical role in maintaining the federal balance.

Given the broad scope of potential federal regulatory authority under current law, preemption is the most critical piece of the Court's federalism doctrine in terms of preserving meaningful state autonomy. By ending state regulatory authority so far as preemption extends, an unduly expansive preemption doctrine undermines the core values of

federalism—that is, the states' ability to respond to geographically divergent conditions and voter preferences, to experiment with innovative policy solutions, and to compete with other jurisdictions to offer the most attractive mix of policies to businesses and individuals. *See generally Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991); *Wyeth*, 555 U.S. at 583-84 (Thomas, J., concurring in the judgment). Broad preemption of state law in the field of medical regulation, for example, would end state experimentation as to the best ways to generate new information concerning drug safety and to compensate victims of unsafe products. *Cf. United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring) (stressing the value of state experimentation). Preemption thus poses a greater threat to state autonomy than, for example, attempts to subject the states to damages liability, *see, e.g.*, *Seminole Tribe v. Florida*, 517 U.S. 44 (1996), or the extreme (but largely symbolic) instances of commerce clause legislation that the Court has struck down as exceeding Congress's constitutional power, *see, e.g.*, *Lopez*, 514 U.S. at 567-68.

Prior to the New Deal, this Court's doctrine of "dual federalism" severely constrained preemption by simply foreclosing federal regulation in many areas. But with the Court's abandonment of dual federalism in cases like *Wickard v. Filburn*, 317 U.S. 111 (1942), the enumerated powers doctrine became a considerably less important constraint on the scope of federal law. *See generally* Young, 2011 Sup. Ct. Rev. at 257-61. Unless this Court is prepared radically to narrow the scope of Congress's authority under the Commerce and Necessary and Proper Clauses, the scope of federal regulation and the

corresponding zone of state autonomy will be largely defined by *Congress*'s choices. *See, e.g., AT&T v. Iowa Utils. Bd.*, 525 U.S. 366 (1999) (interpreting the 1996 Telecommunications Act to transfer a vast swath of regulatory authority over the local telephone market from state regulators to the Federal Communications Commission). Two aspects of that situation are vital: First, Congress—to at least some extent—represents the states. And second, Congress can make law only through a relatively arduous process. Both these aspects of the constitutional scheme suggest that courts should find preemption only in light of clear congressional intent or a serious conflict with a clear congressional policy.

This Court has long suggested that the primary institutional safeguard for state autonomy in our system derives from the states' representation in the national political process. *See San Antonio Metro. Transit Auth. v. Garcia*, 469 U.S. 528 (1985). The importance of that representation undergirds this Court's oft-stated rule that "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic*, 518 U.S. at 485. It also supports *Rice*'s presumption, because "a presumption against preemption promotes legislative deliberation" about the impact of proposed federal statute on state law. Robert R. M. Verchick & Nina Mendelson, *Preemption and Theories of Federalism*, in Preemption Choice: The Theory, Law, and Reality of Federalism's Core Question 13, 23 (William W. Buzbee ed. 2009). As Justice O'Connor wrote for the Court, "'to give the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests.'" *Gregory*, 501 U.S. at

464 (quoting Laurence H. Tribe, *American Constitutional Law* § 6-25 (2d ed. 1988)).

Our constitutional structure augments these "political safeguards" of federalism with *procedural* safeguards as well. As Bradford Clark has explained, "[t]he lawmaking procedures prescribed by the Constitution safeguard federalism in an important respect simply by requiring the participation and assent of multiple actors. . . . In short, the imposition of cumbersome federal lawmaking procedures suggests that the Constitution 'reserves substantive lawmaking power to the states and the people both by limiting the powers assigned to the federal government and by rendering that government frequently incapable of exercising them.'" Clark, 79 Tex. L. Rev. at 1339-40 (citations omitted). Justice Thomas has thus rightly read the Supremacy Clause to require "that pre-emptive effect be given only to those federal standards and policies that are set forth in, or necessarily follow from, the statutory text that was produced through the constitutionally required bicameral and presentment procedures." *Wyeth*, 555 U.S. at 586 (Thomas, J., concurring in the judgment). This "structural limitation" precludes implied preemption "based on [the Court's] interpretation of broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not contained within the text of federal law." *Id.* at 586, 587.

These general propositions do not, of course, decide particular cases. But they do underscore the importance of the arguments set out earlier in this part: that *Rice*'s presumption against preemption should be scrupulously enforced; that impossibility

preemption should be narrowly construed; and that preemption should not be found based on an open-ended construction of Congress's "purposes and objectives." The importance of preemption to federalism doctrine generally also reinforces the arguments that follow, which argue for reading state law to complement, rather than contradict, the federal regulatory scheme at issue in this case.

II. STATE TORT LAW COMPLEMENTS THE FEDERAL REGULATORY SCHEME FOR PRESCRIPTION DRUGS.

When it enacted the FDCA, "Congress took care to preserve state law." *Wyeth*, 555 U.S. at 567. The 1962 amendments to the FDCA included a savings clause, "indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." *Id.* (quoting FDCA, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962)). And while Congress has added an express preemption provision for medical devices, it has conspicuously failed to do so for prescription drugs. *Compare Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (finding preemption under the medical devices provision). As the Court observed in *Wyeth*, "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices . . Congress has not enacted such a provision for prescription drugs." 555 U.S. at 574.[2]

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[2] *See also id.* at 575 ("[Congress's] silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend

Wyeth thus rejected the broad arguments advanced both by Petitioners and the Government in this case that the FDA approval process, combined with post-marketing review of drugs by the agency, is the exclusive protection for consumers. In recognizing the complementary role of state tort law, moreover, *Wyeth* necessarily rejected broad claims that juries are incapable of making judgments about medical safety. Rather, this Court's cases have recognized that state tort law serves valuable functions not fully accounted for by federal law: state law compensates persons injured by unsafe products, provides incentives and a forum for the development of new information about drug safety, and compensates for the limited resources of the FDA. These functions are no less essential with respect to generic drugs than with respect to brand name products. They are also equally applicable to claims of defective design as to claims of failure to warn. In each of these areas, there is no reason to depart from *Wyeth*'s conclusion that Congress intended to preserve the complementary role of state law.

FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166-67 (1989) ("The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them."). In the context of the prescription drug regime, Congress's failure to enact an express preemption clause simply underscores the savings clause enacted as part of the 1962 amendments.

A. This Court's cases recognize the ways in which state tort law complements federal regulation of prescription drugs.

The *Wyeth* Court noted that "Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs. . . . Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers." 555 U.S. at 574. Moreover, Congress "may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.* Later in the opinion, the Court explained that

> The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information.

555 U.S. at 578-79 (citing recent studies indicating that the FDA's post-marketing review process is inadequate, standing alone, to ensure public safety).

This Court has rejected efforts to construe the federal scheme as leaving no room for state tort law. In *Wyeth*, the FDA had promulgated a "preamble" in which it "declared that the FDCA establishes 'both a

floor and a ceiling,' so that 'FDA approval of labeling . . . preempts conflicting or contrary State law.'" 555 U.S. at 575 (citations omitted).[3] Nonetheless, this Court rejected the argument for preemption, observing that "Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight. Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case." 555 U.S. at 581.

Wyeth's conclusion that state tort liability does not obstruct the purposes and objects of the FDCA scheme forecloses Petitioners' argument for implied preemption here. It also forecloses, *a fortiori*, any argument that it is "impossible" to comply with both the FDA's approval of sulindac and a state tort judgment finding sulindac to be defectively designed. Both the purposes and objects argument in *Wyeth* and Petitioners' impossibility argument here are predicated on the notion that FDA regulation provides both a ceiling and a floor—that is, that no drug can be marketed without FDA approval, but that approval confers a *right* to market that drug without interference from state law. Given that impossibility is an even more demanding standard for preemption than purposes and objects, *Wyeth*'s rejection of the latter necessarily disposes of the former.

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[3] The preamble "further stated that certain state-law actions, such as those involving failure-to-warn claims, 'threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.'" 555 U.S. at 575-76.

B. State law's complementary functions are no less important when they involve generic drugs or defective design claims.

Nothing in *Wyeth*'s vision of state and federal law as complementary safeguards for public health is limited to either failure-to-warn claims or branded drugs. As the facts of this case illustrate, the victims of defectively designed drugs need compensation just as do those injured by a failure to warn. And the incentives provided by state law for manufacturers to continue to identify and respond to safety risks, even after FDA approval of a drug, are no less important if danger stems from a drug's design rather than its warning.

It is true that, in *Wyeth*, federal law specifically permitted manufacturers of branded drugs to change their labels (pending FDA approval) in order to comply with state tort law duties to warn. Here, by contrast, the state-law finding of defective design goes to the underlying product itself, not simply the label. But unless the FDCA preempts defective design claims altogether, it will always be possible that a particular product might be so inherently defective that it cannot be made safe—that is, that the manufacturer may be forced either to compensate those injured by the product in the future or to withdraw the product from the market. To say that putting the manufacturer to that choice is irreconcilable with federal pre-market approval of the drug is to hold *all* design defect claims categorically preempted. If Congress had intended such a radical impact on state tort law, it surely would have said something about it in the statute. *Cf. Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457,

468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").

Generic drug manufacturers are in the same boat as branded manufacturers with respect to defective design claims. After all, a branded manufacturer forced to redesign its drug would have to secure FDA approval for the new version, just as a generic manufacturer who redesigned a generic drug would, in effect, be seeking approval for a new version of the drug altogether. Hence, although generic and branded manufacturers have different obligations with respect to failure to warn claims, their obligations are identical with respect to claims predicated on the drug's design or composition. In the face of a successful defective design claim, both branded and generic manufacturers have the same three options: seek FDA approval for a new, redesigned drug; stop selling the old drug; or simply choose to compensate any person injured by the drug. The special obligations and policies of the Hatch-Waxman Act can thus add nothing to Petitioners' impossibility argument, and in any event, that Act evinces no congressional intent categorically to preempt design defect claims.

Moreover, as Justice Sotomayor noted in her *PLIVA* dissent, generic drugs "dominate the market. . . . Ninety percent of drugs for which a generic version is available are now filled with generics. In many cases, once generic versions of a drug enter the market, the brand-name manufacturer stops selling the brand-name drug altogether." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2584 (2011) (citations omitted). Given the market

dominance of generics, state law can hardly serve as a complementary back-end safety regime if it is limited to claims against branded drug manufacturers.

III. The New Hampshire Tort Rule at Issue Here Does Not Conflict with the Federal Regulatory Scheme.

Resolution of conflict preemption claims requires careful interpretation not only of the federal statutory scheme at issue but also of the content of the relevant state law. The parties in this case do not agree as to the proper characterization of the state law duties here. *Amici* agree with Respondent that New Hampshire's rule of strict liability for unreasonably dangerous products is best read not as an obligation to withdraw defective products from the market, but rather simply as a duty to compensate the (possibly very small) class of individuals who are injured by those products. Read in this way, the state law is not inconsistent with the FDA's pre-market judgment that the drug may be marketed because, overall, its benefits outweigh its risks. Rather, drug manufacturers may comply with both state and federal law by marketing their product while effectively insuring the small class of persons harmed by that product for their injuries.

On the other hand, Petitioners read New Hampshire law as a duty *not* to market an unreasonably dangerous product. Even if that reading were correct, there should be no preemption in this case. Design defect claims may require a manufacturer to stop selling a particular product, and there is no clear evidence in this case that Congress intended categorically to preempt design

defect claims. Nor can the preemption rationale of *PLIVA*, which relied upon the special constraints that federal law imposes on generic manufacturers, be extended to cover cases in which the underlying product itself has been found to be unreasonably dangerous.

A. New Hampshire law does not require Petitioners to stop selling their drug, and the obligation to compensate injured persons does not conflict with federal law or policy.

State law does not require a drug manufacturer in Petitioner's shoes either to violate federal law or to stop selling its product. It can, after all, simply choose to continue marketing its product while paying damages to persons injured by the drug. The New Hampshire Supreme Court has made clear that, under state law, liability is not premised on the breach of a legal duty: "Legal liability is said to be strict when it is imposed even though the defendant has committed no legal fault consisting of the violation of a common law or statutory duty." *Bagley v. Controlled Env't Corp.*, 503 A.2d 823, 825 (N.H. 1986) (Souter, J.); *see also id.* at 559 (identifying New Hampshire's "cause of action for damages . . . for the benefit of the user or consumer of an unreasonably dangerous and defective product" as "based on strict liability"). Similarly, New Hampshire products liability law does not premise liability on a duty to improve the product's design. *See Kelleher v. Marvin Lumber & Cedar Co.*, 891 A.2d 477, 492 (N.H. 2005) (noting that "the plaintiff is not required to present evidence of a safer alternative design"). And damages, under New Hampshire law, are imposed solely to compensate the victim rather than to

impose incentives for manufacturers to change their products. *See, e.g., Stewart v. Bader*, 907 A.2d 931, 943 (N.H. 2006) ("Punitive damages are not allowed in New Hampshire" and "'[n]o damages are to be awarded as a punishment to the defendant or as a warning and example to deter him and others from committing like offenses in the future.'" (quoting *Aubert v. Aubert*, 529 A.2d 909, 914 (N.H. 1987))).

If the incidence of SJS/TEN is actually very low, and the drug is beneficial and therefore valuable to many other persons, then the most rational course for a manufacturer may well be simply to continue selling its product and compensate the small number of people who develop harmful side effects. The primary function of tort law in this setting is simply to shift the financial loss to the party best able to bear it. *See, e.g., Heath v. Sears, Roebuck & Co.*, 464 A.2d 288, 293 (N.H. 1983) (observing that "the risk of liability is best borne by the companies that profited from their sale, rather than by the unfortunate individual consumers").[4] A manufacturer's decision to continue to market a product known to cause bad reactions in a small but unidentifiable subset of consumers would, in effect, amount to a decision to insure those unfortunate patients by compensating

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[4] Even in contract law, it has long been recognized that some agreements are best interpreted not as imposing an obligation to perform but simply an obligation to pay damages in the event that one does not or cannot perform. Justice Holmes famously observed that "in the case of a binding promise that it shall rain to-morrow, the immediate legal effect of what the promisor does is, that he takes the risk of the event, within certain defined limits, as between himself and the promisee." Oliver Wendell Holmes, Jr., *The Common Law* (1881), in 3 The Collected Works of Justice Holmes 268 (S. Novick ed. 1995).

them for their loss. This is all that New Hampshire law requires in strict liability cases that are not based on a failure to warn.

In other settings, of course, tort law may perform other functions—including the function of shaping defendants' and potential defendants' behavior. But that hardly means that New Hampshire should not be permitted to erect a strict liability scheme of its own design, focused on compensating victims rather than imposing duties on manufacturers. *Wyeth*, after all, identified compensation of victims as one of the critical functions that the FDCA leaves to state law. State tort duties should thus not always be seen as competing "requirements" of the sort generally preempted by certain federal regulatory regimes. The "requirements" imposed by federal law, after all, are like property rules: they can be enforced by injunctions or even criminal prosecution. State tort law, on the other hand, generally imposes a liability rule, which allows the defendant an option to simply pay damages while continuing in his activity. *Cf.* Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules and Inalienability: One View of the Cathedral*, 85 Harv. L. Rev. 1089 (1972). To say that it is "impossible" to comply with federal and state law under these circumstances is to elide this important distinction.

B. This Court's recognition that state common law liability may impose a "requirement" under certain federal statutes is not a reason to disregard the New Hampshire Supreme Court's interpretation of state law.

Preemption depends not only on the intent of Congress but also on how that intent bears on the particular laws of each state. In this case, Petitioners propose to establish a uniform rule of preemption by treating "state tort law" as a generic category, without taking seriously the ways that state law may vary. This approach might be intellectually tidy, but it subverts basic purposes of our federalism. As Justice Kennedy has observed, "the theory and utility of our federalism are revealed" when "the States . . . perform their role as laboratories for experimentation to devise various solutions where the best solution is far from clear." *Lopez*, 514 U.S. at 581 (Kennedy, J., concurring). Whether state law conflicts with Congress's purposes may turn importantly on features of a particular state's common law regime—whether it allows punitive damages, for example, or imposes a duty not simply to pay compensation but also to withdraw a product from the market.

Here, both the Petitioner's and the Government's amicus briefs reject Respondents' reading of state law, suggesting that this Court has already determined that state tort liability *always* imposes "requirements" on manufacturers. *See* Petitioner's Brief at 41-42; Brief of the United States as *Amicus*

Curiae in Support of Petitioner, at 15-16. In *Riegel*, this Court said:

> Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's "requirements" includes its common-law duties. As the plurality opinion said in *Cipollone*, common-law liability is "premised on the existence of a legal duty," and a tort judgment therefore establishes that the defendant has violated a state-law obligation. [*Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 522 (1992).] And while the common-law remedy is limited to damages, a liability award "'can be, indeed is designed to be, a potent method of governing conduct and controlling policy.'" *Id.* at 521.

552 U.S. at 324. In *Riegel*, *Cipollone*, and a number of similar cases, the Court had to construe express preemption clause in various federal statutes foreclosing state imposition of "requirements" different from or in addition to those imposed by federal law. In those cases, the question was how *Congress* understood state tort law and what it intended to preempt.[5]

This Court's opinion in *Riegel* repeatedly stressed the importance of the express preemption clause for

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[5] We would not rule out the possibility that a state tort regime might feature a rule that fell outside Congress's view of "requirements," but whether Congress's language covered such a rule would remain a question of federal law. In the absence of such statutory language, however, this Court must look to what state law actually does, as understood by the state courts.

state law "requirements." *See, e.g.*, 552 U.S. at 326, 327. Moreover, there is good reason not to extend *Riegel*'s interpretation of "requirements" in the Medical Devices Amendments beyond its original context. The statutory text does not expressly address state tort law, and the *Medtronic* plurality concluded that "when Congress enacted [the MDA's preemption provision] it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions." 518 U.S. at 489 (plurality opinion). *Riegel*, moreover, did not consider whether a state law regime that expressly imposed no duty on medical device manufacturers would be a preempted "requirement."

This Court's opinion in *Bates* strongly suggests that New Hampshire's strict liability rule would not be preempted even under an express preemption clause foreclosing state "requirements." Petitioner's argument is that holding it liable would induce it to either alter the design of its drug (in violation of federal law) or to stop selling that drug. Similarly, in *Bates*, the court of appeals found preemption on the ground that "a finding of liability on these claims would 'induce Dow to alter [its] label.'" 544 U.S. at 445 (citation omitted). This Court rejected, however, "[t]his effects-based test" on the ground that it "finds no support in the text of [the express preemption provision], which speaks only of 'requirements.'" *Id.* In language strikingly relevant to this case, the Court explained that

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an

> examination of the elements of the common-law duty at issue . . . it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants).

Id. (citing *Cipollone*, 505 U.S. at 524 (plurality opinion)). Even in the presence of an express preemption clause, then, *Bates* makes two crucial points: first, even federal law does not categorically classify state tort rules as "requirements" governing defendants' behavior, but rather requires "an examination of the common-law duty at issue"; and second, federal preemption doctrine differentiates between state law rules that actually *require* a change in the manufacturer's behavior and those that simply impose costs that might induce a similar effect.

There is, in any event, no such express preemption clause here. The question is simply whether state law imposes a duty that makes it impossible to comply with both state and federal law, or that interferes with the purposes of Congress's regulatory scheme. The question is thus not what Congress meant by a statutory term, but rather what state law in fact requires. That is a question of state law, and this Court's precedents cannot be read as definitive constructions of that law—even in the unlikely event that this Court intended them as such. The meaning of state law must be evaluated state-by-state, and the final authority on that question is each state's supreme court. *See, e.g.*, *Mullaney v. Wilbur*, 421 U.S. 84, 692 (1975) ("This

Court . . . repeatedly has held that state courts are the ultimate expositors of state law . . . and that we are bound by their constructions except in extreme circumstances not present here." (citing, *inter alia*, *Murdock v. City of Memphis*, 87 U.S. (20 Wall.) 590 (1875))).

The rule that this Court is bound by the New Hampshire Supreme Court's interpretation of its own law should hardly require explication. It is grounded not only in the federal courts' general lack of authority to supply legal rules of decision in the absence of federal statutes or constitutional provisions, *see Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), and this Court's lack of jurisdiction over state law questions in appeals from the state supreme courts, *see Murdock*, 87 U.S. (20 Wall.) at 635, but also the superior expertise of the state courts concerning state law and the need for comity among courts in a federal system. The across-the-board characterization of state tort law as imposing regulatory requirements in cases like *Riegel* is thus not binding here, and that characterization must give way if the state courts have in fact construed state law otherwise.

C. Even if state law *did* require Petitioners to stop selling their product, that would not conflict with the federal regulatory scheme.

The tort claims in this case are not preempted even if New Hampshire law is best read as imposing a duty not to market the unreasonably dangerous product. *PLIVA* found impossibility preemption based on the notion that a successful failure-to-warn claim would impose a legal duty on generic

manufacturers to do something that federal law did not permit them to do: change their drug's label. *See* 131 S. Ct. at 2577 ("It was not lawful under federal law for the Manufacturers to do what state law required of them."). Any such change, after all, would violate the federal requirement that generic drugs' labeling be exactly the same as that of the brand name drug. The present case appears, at first blush, to pose a similar dilemma: Just as generic drug manufacturers cannot change their label, they also cannot change the chemical composition of their drug in response to a state-law finding that the drug is unreasonably dangerous. And while a generic manufacturer remains able to respond to that finding by ceasing to market the drug at all, that option—as Judge Boudin recognized, *see Bartlett v. Mutual Pharm. Co.*, 678 F.3d 30, 38 (1st Cir. 2012)—was available to the defendants in *PLIVA*, too.

The crucial difference, however, is that *PLIVA* came to this Court without any claim that the drug's risks outweighed its benefits—only a claim of failure-to-warn. The plaintiffs effectively conceded, in other words, that the drug in that case was appropriate to market. In that circumstance, it is unreasonable to force the manufacturer nonetheless to stop selling the drug simply because federal law forbids it to change the inadequate label. But in the present case, where the plaintiff's strict liability claim is precisely that the drug is unreasonably dangerous, obligating the manufacturer to take the drug off the market would be more reasonable. After all, it is likely that many products subject to successful design defect claims cannot be reengineered to an adequate level of safety, so that the only alternative to tort liability is to take them off the market. If

Congress intended to allow defective design claims *at all*, for branded drugs or generics, then that decision necessarily includes scenarios where a manufacturer may have to cease marketing its unsafe product to avoid the risk of future liability.

Congress could, of course, preempt such claims if it so wished. But that simply highlights the crucial difference between this case and *Wyeth*, on the one hand,[6] and *Riegel* on the other. A state law duty to stop selling a product might well qualify as a "requirement" under the express preemption language at issue in *Riegel* (and *Bates*). But Congress enacted no such statute here. As our discussion in Part I makes clear, preemption is about *Congress*'s action and *Congress*'s clear intent. That body's deliberate decision not to extend express preemption to the entire regime of FDA premarket approval should make a difference here.

CONCLUSION

The judgment of the United States Court of Appeals for the First Circuit should be affirmed.

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[6] As we have already explained, branded and generic manufacturers stand in precisely the same shoes with respect to design defect claims that do not involve a failure to warn. *See supra* Part II.B. That is particularly true of the one-molecule drug at issue in this case.

Respectfully submitted,

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AMICUS CURIAE BRIEF

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In the Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC., PETITIONER

v.

KAREN L. BARTLETT, RESPONDENT

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR RANBAXY PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., IMPAX LABORATORIES, INC., AMNEAL PHARMACEUTICALS, LLC, AURO PHARMA USA, INC., ALKEM LABORATORIES, LTD., PERRIGO COMPANY AND MYLAN, INC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the First Circuit erred in holding that federal law does not preempt state law design-defect claims against generic pharmaceutical products because—despite the conceded conflict between such claims and the federal laws governing generic pharmaceutical design—the makers of generic pharmaceuticals can simply stop making their products.

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INTRODUCTION AND INTEREST OF *AMICI CURIAE*[*]

Recognizing that the Hatch-Waxman Act requires generic and brand-name drugs to carry the "same" labels—which generic manufacturers may not change—this Court recently held that federal law preempts state-law failure-to-warn claims against generics. *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2572 (2011). Despite *Mensing*'s sameness rationale, and its recognition that generics likewise must be "identical in active ingredients, safety, and efficacy" (*id.* at 2574 n.2), the court below held that state design-defect claims against generics are *not* preempted. The court offered no basis for distinguishing between failure-to-warn and design-defect claims. Yet it reasoned that the conceded conflict between design-defect claims and federal law can be avoided because generic drug makers "can choose not to make the drug at all." Pet. App. 10a.

This ruling ignores both the sameness rationale of *Mensing* and its result. After all, the conflict between the federal labeling requirements and state tort duties in *Mensing* likewise could have been avoided if the defendant generic drug makers had chosen "not to make the drug at all." And insofar as there is any basis for distinguishing between labeling-based and design-based claims for purposes of preemption, the case for preemption is even *stronger* when it comes to pharmaceutical product design.

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[*] The parties consented to the filing of this brief. The letters of consent are on file with the Clerk. In accordance with Rule 37.6, *amici* state that no counsel for any party authored this brief in whole or in part, and that no person or entity, other than the *amici*, has contributed monetarily to the preparation or submission of this brief.

Labels do not exist for their own sake. They are signposts concerning the *product* on the inside of the packaging. That is, generic labels must track their FDA-approved brand counterparts for a reason—namely, that the generic products represented by the labels likewise must be the same as their branded counterparts. A label no more controls the content of the packaged product than a tail wags a dog. And since labels are simply a proxy for their products, *Mensing* necessarily requires preemption. The First Circuit's contrary view not only runs afoul of the Hatch-Waxman Act, it is analytically incoherent.

Amici curiae are manufacturers and sellers of generic drugs. They or their affiliates are defendants in thousands of suits seeking to impose liability upon them under state-law standards with which they cannot comply without violating federal law. The concern of these *amici* is that the state-by-state approach to labeling rejected in *Mensing* not be revived under a new name. By disregarding the essential unity between labels and products, the decision below exposes generic drug makers to the same conflicting state law duties already rejected in *Mensing*. That is not what Congress intended when it commanded that a generic drug be a copy of the brand.

The decision below must be reversed.

STATEMENT

This case involves a collateral attack on the label of an FDA-approved prescription drug, after this Court in *Mensing* (in the words of the court below) "foreclosed a direct attack on the adequacy of the label." Pet. App. 4a. The drug at issue, sulindac, is a non-steroidal anti-inflammatory drug manufactured by petitioner. Pet. App. 1a-4a. Respondent suffered injuries and filed suit against petitioner after she was prescribed sulindac by her doctor, who "admitted that he had not read the box label or insert." Pet. App. 4a.

Respondent alleged that petitioner's product was defectively designed. When petitioner responded that federal law required its generic sulindac to be a *copy* of the branded drug, and that any design-defect claim was therefore preempted, the district court disagreed. According to that court, "one way to avoid violating state law * * * would be to refrain from distributing [the drug] at all." Pet. App. 165a. At trial, respondent's primary design-defect theory was that sulindac's risk exceeded its benefits, rendering it unreasonably dangerous and requiring its removal from the market. Pet. App. 4a-5a. The jury agreed.

While petitioner's appeal was pending, this Court held that, on account of the "ongoing federal duty of sameness" requiring that generic drugs copy their brand-name counterparts, federal law preempts state-law failure-to-warn claims against generic drug makers. *Mensing*, 131 S. Ct. at 2574-2575, 2577-2578. The upshot of the federal sameness requirements here, petitioner argued, was that petitioner could not comply with state law (as applied by the jury) by selling a version of sulindac materially different than the FDA-approved, branded version.

The First Circuit agreed that petitioner "cannot legally make sulindac in another composition," but, like the district court, reasoned that petitioner "can choose not to make the drug at all; and the FDCA might permit states to tell [petitioner] it ought not be doing so * * * despite what the Supreme Court made of similar arguments in the labeling context." Pet. App. 10a. The court acknowledged that "[t]his is second-guessing the FDA," but justified its decision on the basis of *Wyeth* v. *Levine*, 555 U.S. 555, 575 (2009), which stated in the context of brand-name drugs that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Pet. App. 9a.

The court below further recognized that *Mensing* post-dated *Wyeth* and, because of the generic sameness requirement, required preemption of failure-to-warn claims. Indeed, it recognized that *Mensing* distinguished *Wyeth* on the basis that, unlike generics, a brand-name drug maker could "unilaterally strengthen its warning without prior FDA approval." 131 S. Ct. at 2581; Pet. App. 9a-10a. Yet the court insisted that *Mensing* was a narrow, "carved out" exception to *Wyeth*'s "general no-preemption rule," and that it is up to this Court "to decide whether [*Mensing*'s] exception is to be enlarged to include design defect claims." Pet. App. 9a, 11a. This Court granted certiorari.

SUMMARY OF ARGUMENT

I. By exposing generic drug makers to the same failure-to-warn claims held preempted in *Mensing*—now dressed up as design-defect claims—the decision below puts generic manufacturers in an impossible situation. As the First Circuit itself recognized, if a drug is found to be defectively designed under state law, then generic manufacturers can either market a drug that complies with federal law (*i.e.*, one that has the same design as the brand-name equivalent) and incur substantial tort liability, or they can take the product off the market. Contrary to the First Circuit, however, this "choice" does not resolve the conflict; it confirms that state law is preempted.

After all, the reason generic labels must be the same as their brand-name equivalents is that the products themselves must be the same. And because design drives labeling, design-defect and failure-to-warn claims cannot be distinguished—one is preempted no less than the other.

II. Even if the First Circuit's stop-selling rule otherwise resolved the conflict between a state law purporting to forbid what federal law authorizes (and it does not), preemption is required here for another reason. State regulation of generic drug design would impose burdens that are directly at odds with the purposes and objectives of the Hatch-Waxman Act. The lower cost of generic drug development is precisely what enables generic drug makers to produce safe, affordable products in an efficient manner. But if generics are subject to claims such as the one sanctioned below, then they must either pay large jury verdicts and pull their products from the market or begin conducting comprehensive NDA-style clinical studies for themselves—which is to say, they must

become brands. But that is the very reinvention of the wheel that Congress sought to avoid in creating an abbreviated approval process for generic drugs. Either way, these tort claims threaten to undo Congress's work by raising the prices and decreasing the availability of generic drugs—to the ultimate detriment of consumers.

It is no answer to say that paying damage awards is merely a cost of doing business. If a conflict could be so easily dissipated, the Court could not have ruled as it did in *Mensing* and other prior decisions. Instead, as this Court has repeatedly held, "common law liability is premised on * * * [the defendant's] violat[ion] [of] a state-law obligation. And while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 324 (2008) (internal citation and quotation marks omitted).

Manufacturers and the economy suffer when complex products sold nationally and extensively regulated by the federal government must submit to yet another layer of "diverse, non-uniform, and confusing * * * regulations"—including state tort judgments. See *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 514, 521 (1992) (plurality). Indeed, where product design is not regulated uniformly, one State—even one *jury*—can effectively impose a controversial design upon, or withhold a beneficial product from, the entire nation. And as this Court has consistently observed, "one State's power to impose burdens on the interstate market" is "constrained by the need to respect the interests of other States." *BMW, Inc.* v. *Gore*, 517 U.S. 559, 571 (1996).

Far from imposing such burdens, the Hatch-Waxman process "is designed to speed the introduc-

tion of generic drugs to market." *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). That being so, federal law will not allow juries to decide that a generic drug ruled safe and effective by the FDA must be banned outright, thus multiplying costs and impeding the drug's availability to consumers in other States. Juries generally lack the institutional expertise needed to make judgments about the design of complex pharmaceutical products. As a practical matter, moreover, for generic drug makers seeking to distribute their products nationwide, a "stop selling" rule in just one State is likely to end the drug's sales in every State, as the cost-structures and logistical realities of the industry do not support a checkerboard approach to distribution.

III. Finally, if the fact that a manufacturer can "choose not to make [its product] at all" (Pet. App. 10a) allowed plaintiffs to skirt preemption, then conflict preemption could never be established for federally regulated manufacturers. *Any* conflict between state tort law and federal requirements—whether related to labeling, packaging, design, or something else—could be avoided by abandoning the product. Not surprisingly, this Court has repeatedly found conflict preemption despite the availability of a "choice" to cease marketing the allegedly defective product. *E.g.*, *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861 (2000); *Cipollone*, 505 U.S. at 521.

For all these reasons, this Court should reject the stop-selling rule adopted by the court below, and confirm that state-law design claims against generic drugs are categorically preempted.

ARGUMENT

I. For purposes of preemption under the Hatch-Waxman Act and *Mensing*, design-defect and failure-to-warn claims are inextricably intertwined.

According to the First Circuit, "it is up to the Supreme Court to decide" whether the rule of *Mensing* should be "enlarged" to cover design-defect claims. Pet. App. 11a. But no "enlarging" is needed. The reasoning of *Mensing* not only directly applies here, it applies *a fortiori*.

A. Hatch-Waxman requires a generic drug to be a copy of a brand-name drug, and thus identical in active ingredients.

As the First Circuit itself observed, under Hatch-Waxman, "[petitioner] cannot legally make sulindac in another composition" from that of the brand. Pet. App. 10a. Yet the court failed to draw the conclusion that necessarily follows from this premise: Because federal law dictates the design of a generic drug, state law may not hold that design "defective."

For new drugs (*i.e.*, brand-name products), a manufacturer must submit a new drug application ("NDA") establishing that the drug is safe and effective when used as labeled. 21 U.S.C. § 355(b); 21 C.F.R. § 314.50. To that end, an NDA must include the following: (1) data demonstrating that the drug is safe and effective; (2) analysis of the drug's composition; (3) an explanation of the methods and controls used for manufacturing, processing, and packing the drug; and (4) proposed labels. 21 U.S.C. § 355(b)(1)(A)-(F); 21 C.F.R. § 314.50(d)-(f). Further, before filing an NDA, the brand-name manufacturer must be authorized to conduct clinical trials to estab-

lish the drug's safety and efficacy. 21 U.S.C. § 355(i); 21 C.F.R. §§ 312.2, 312.20.

The NDA process is exhaustive. A typical NDA spans thousands of pages and is grounded in clinical trials conducted over several years. GAO, *New Drug Development, Report to Congressional Committees*, 26 Biotech. L. Rep. 82, 94 (2007). On average, evaluating an NDA takes the FDA some 442 days. *Id.* at 86.

The abbreviated ("ANDA") process for generic drugs is altogether different. "Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Caraco*, 132 S. Ct. at 1676 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)). That is, a generic is "designed to be a copy" of the brand-name drug. *Mensing*, 131 S. Ct. at 2574 n.2.

To ensure its safety, the generic copy must be "identical" to an approved NDA drug with respect to active ingredient, route of administration, dosage form, strength, and conditions of use. 21 U.S.C. § 355(j)(2)(A)(i); 21 C.F.R. § 314.92(a)(1).[1] Moreover,

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[1] In limited circumstances and subject to the FDA's discretion, the ANDA process may also be used for a drug with one different active ingredient, or whose route of administration, dosage form, or strength differs from the NDA product. 21 U.S.C. § 355(j)(2)(C); 21 C.F.R. § 314.93; see generally 57 Fed. Reg. 17950, 17951-17952 (Apr. 28, 1992). But no such difference is involved in this case, and no such difference factored into the decision below. In addition, as discussed below (at 31-33), the Court in *Mensing* considered and unequivocally rejected the argument that conflict preemption can be defeated based on what a generic manufacturer *could have* asked FDA to do, and how FDA *could have* responded. 131 S. Ct. at 2578-2579.

an ANDA must establish that the generic drug is therapeutically equivalent or "bioequivalent" to, and will be given the same labeling as, the brand-name drug. 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94(a). Use of the same label is critical because "[d]rug labeling serves as the standard under which FDA determines whether a product is safe and effective." 50 Fed. Reg. 7452, 7470 (Feb. 22, 1985).

Generic manufacturers need not (and do not) produce evidence of safety or efficacy by conducting clinical trials. That has already been done by the brand; no trials are needed to ensure the safety and efficacy of the copy. Rather, the point of Hatch-Waxman was "to speed the introduction of low-cost generic drugs to market." *Caraco*, 132 S. Ct. at 1676 (citing *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990)).[2] To that end, Congress directed the FDA to approve any product that is a true generic—*i.e.*, bioequivalent to the branded drug and sold with identical labeling. The FDA will reject an ANDA drug that flunks these criteria. 21 C.F.R. § 314.127.

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[2] See also, *e.g.*, "P.L. 98-417, Drug Price Competition and Patent Term Restoration Act," H.R. Rep. No. 857(I), 98th Cong., 2d Sess. (1984), reprinted in 1984 U.S.C.C.A.N. 2647, Pet. App. 122a; New Drug Application: Hearings on H.R. 3605 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong., 1st Sess. (1983), Pet. App. 114a; Drug Price Competition and Patent Term Restoration Act of 1984, Committee Notes, 130 Cong. Rec. 24416, H.R. 3605 (Sept. 6, 1984), Pet. App. 136a; Drug Price Competition and Patent Term Restoration Act, Committee Notes, 130 Cong. Rec. 24970, S. 1538 (Sept. 12, 1984).

In short, to the extent that state tort law may impose a different standard for the design of an FDA-approved drug, it is impossible for a generic manufacturer to comply. Whatever choices a brand-name manufacturer may have, the generic manufacturer has none. That is why generic manufacturers are required to submit the proposed product and the proposed label to the FDA at the same time. 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8). The ANDA product must be same as the NDA product; the generic drug maker's federal obligations are as simple as that.

The court below did not adopt a different reading of these straightforward federal requirements. Instead, it declared that generic manufacturers have a "choice": Although federal law imposes a duty of "sameness" on generic products, in any State where a jury concludes that the law requires a different design than that adopted by the brand-name manufacturer and approved by the FDA, the generic manufacturer can simply cease doing business. Pet. App. 10a.

This analysis is flatly inconsistent with settled principles of conflict preemption, as well as the rationale and result of *Mensing* (where the very same arguments were made and rejected). Further, as discussed below (at 15-19), if allowed to stand, the decision below will make needed generic drugs both more expensive and more scarce—directly harming consumers and undermining Congress's intention in passing the Hatch-Waxman Act.

B. The notion that failure-to-warn claims are preempted but design-defect claims are not is analytically incoherent.

The decision below is also analytically incoherent. Drug product design drives labeling, not the other way around. As the FDA has instructed, "the ANDA product's labeling must be the same as the listed drug product's labeling *because the listed drug product is the basis for ANDA approval.*" 57 Fed. Reg. at 17961 (emphasis added); see also *Mensing*, 131 S. Ct. at 2574 (describing parallel sameness requirements for generic products and labels).

A label no more controls product design than a tail wags a dog. To say, as did the court below, that a state law claim against a *label* is preempted, but a claim against the *product design* is not, is thus fundamentally to misunderstand the nature of the label-product relationship. Indeed, it is to get that relationship exactly backwards. If the labeling claim is preempted, the design-defect claim must be preempted, because the label is merely a proxy for the product. The reason a generic's label must track the brand's label verbatim is that the product itself must likewise be "the same as" the branded product.

Just last Term, in finding preemption under another federal statute, this Court recognized the close relationship between failure-to-warn and design-defect claims. See *Kurns* v. *Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1268 (2012) (noting that "[a] failure-to-warn claim alleges that the product itself is unlawfully dangerous unless accompanied by sufficient warnings or instructions" and explaining that, where "failure-to-warn claims are * * * directed at the equipment [at issue]," the "'gravamen' of

[those] failure to warn claims" is sufficiently similar to warrant preemption under the same rationale). Indeed, many jurisdictions (including New Hampshire, where this case originated) recognize that an adequate warning is sufficient to defeat design-defect claims. Pet. App. 7a; *Fellows* v. *USV Pharm. Corp.*, 502 F. Supp. 297, 300 (D. Md. 1980) (collecting cases establishing that "prescription drugs are not considered unusually dangerous under section 402A, and the manufacturer will not incur liability under that section, unless the manufacturer has failed to provide adequate warnings of the drug's possible dangers"). That is all the more true in cases involving pharmaceuticals.

As the Restatement (Second) of Torts explains, a product may be "unavoidably unsafe," a classification "common in the field of drugs," which often have undesirable side-effects and carry serious risks. "Such a product, properly prepared and accompanied by proper directions and warning, is not defective." Restatement (Second) of Torts, § 402A cmt. k (1965); see also *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068, 1077 (2011) ("Comment k exempts from * * * strict-liability rule 'unavoidably unsafe' products."). The reason is that the potential side-effects of such drugs are not a product of bad design; they are simply an unavoidable risk. In fact, the First Circuit itself acknowledged that, under New Hampshire law, claims of design-defects can collapse into claims of failure-to-warn. Pet. App. 7a.

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In summary, in the context of prescription drugs, "design-defect" claims are a red herring. There is no meaningful distinction between such claims and

claims for failure-to-warn: The law requires generic labels *and* products to match their branded counterparts; labels are derived from the products, not vice versa; and the adequacy of generic product warnings (which *Mensing* immunizes from challenge) is a complete defense to design-defect liability.

It is telling that the court below did not propose any rationale whatsoever for distinguishing these two types of claims in substance. But given that any attack on the drug labels here is preempted under *Mensing*, preemption of any attack on the design of the labeled products should be a foregone conclusion—as every other court had recognized before the ruling below. Design-defect claims against generic drugs, no less than failure-to-warn, are preempted.

II. State regulation is an added burden on generic manufacturers and consumers and, as such, conflicts with the federal regime.

The decision below is not only unlawful and analytically unsound, it is also destabilizing to the generic drug industry and threatens significant costs to consumers and the nation's health care system—all in direct conflict with the Hatch-Waxman Act's objectives. State law juries cannot be permitted to "second guess[] the FDA." Pet. App. 10a. Nor can this conflict be resolved on the theory that paying tort judgments is merely a cost of doing business. As a long line of this Court's precedents confirms, common law obligations, enforced by jury verdicts, must be obeyed no less than positive enactments of state law.

Further, of all types of tort claims, design-defect claims—particularly those involving complex pharmaceutical products—are among those least suitable for resolution by juries and most suitable for preemp-

tion. Yet instead of *federal preemption*, the First Circuit authorized *state prohibition*. This turns the Supremacy Clause on its head. After all, where the FDA, acting in response to Congress's instructions, has declared a product "safe and effective," it is plainly "to the Contrary" to ban the product. U.S. Const., Art. VI, cl. 2. Indeed, it is both unlawful and unwise to deprive citizens in "prohibition States" of low-cost, federally approved medicines, while adding to the burdens on drug makers attempting to serve a national market.

A. State regulation of product design would raise prices and decrease the availability of generic drugs—in square conflict with the central purposes and objectives of the Hatch-Waxman Act.

1. As discussed above, under *Mensing*'s impossibility-preemption analysis, conflicting federal and state obligations cannot be reconciled by the First Circuit's stop-selling rule. But even if they could, requiring a generic manufacturer to "comply" with federal law by withholding its product from the market would defeat Congress's carefully calibrated approach to introducing generic drugs, which gave birth to the modern generic drug industry that ultimately benefits consumers. See *Arizona* v. *United States*, 132 S. Ct. 2492, 2501 (2012) (conflict preemption includes not only cases where "compliance with both federal and state regulations is a physical impossibility," but also "those instances where the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress") (citations omitted). "[I]t is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs

more quickly and cheaply to the public." *Mensing*, 131 S. Ct. at 2582.

This was not happenstance. The animating purpose of the Hatch-Waxman Act was to *increase* the availability, and *lower* the cost, of generic drugs. See *Caraco*, 132 S. Ct. at 1676; *supra* n.2 (collecting authorities). But allowing state tort claims here would thwart this federal policy by forcing generic manufacturers to undertake comprehensive, NDA-style clinical trials—on pain of substantial liability—effectively turning generics into brands. That is not what Congress intended. Cf. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (explaining that, "[a]s a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants" and may "discourage[] [them] from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer * * * to unpredictable civil liability").

On the contrary, as this Court recognized in *Mensing*, the central and immutable federal obligation imposed on generic manufacturers is to produce a drug "the same as" a branded equivalent. 131 S. Ct. at 2574-2575 & n.2. To be sure, federal law does not forbid generic manufacturers from assessing drug safety and efficacy by conducting independent clinical trials. But it puts the *obligation* to do so on the brands, through the NDA process. If state law can oblige generics to perform the same analysis, the ANDA process is overthrown: Under the old regime, generics had to be priced to reflect the fact that each would-be generic manufacturer independently had to establish safety and efficacy. Congress passed the

Hatch-Waxman Act and created the ANDA process—an *abbreviated* NDA process—precisely to spare generic manufacturers from undertaking unnecessary and duplicative studies, which drive up the cost of needed generic medicines.

To this day, generic companies such as the undersigned *amici* are able to provide generic medicines in an efficient manner—and thus to compete—because of the streamlined Hatch-Waxman process. "While estimates of the cost to bring a new branded drug to market are in excess of a billion dollars, the research and development costs for a new generic drug are only 1 to 2 million dollars." ASPE Issue Brief: Office of the Assistant Secretary for Planning & Evaluation, Office of Science and Data Policy–U.S. Department of Health and Human Services, *Expanding the Use of Generic Drugs* 4-5 (Dec. 2010).[3]

Moreover, "growth in the use of generic drugs has generated substantial savings for American consumers" (*id.* at 2): "In 2010 alone, the use of FDA-approved generics saved $158 billion, an average of $3 billion every week,"[4] and such use has saved "*$1.07 trillion* over the past decade."[5] Not only does

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[3] Available at: http://aspe.hhs.gov/sp/reports/2010/ GenericDrugs/ib.shtml.

[4] FDA, *Facts about Generic Drugs* (Sept. 19, 2012) (citation omitted), available at: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm.

[5] Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.* 1 (4th ed. 2012), available at: http://www.gphaonline.org/sites/default/files/IMS%20Study%20Aug%202012%20WEB.pdf (emphasis added).

increased generic substitution drive down the price of the *brand*, but "[t]he relatively low costs to entry for generic drugs lead to increased competition, which drives prices for generic drugs down dramatically" too. ASPE Issue Brief, *supra*, at 4, 5. As the FDA has found, "the first [generic] entrant has a relatively small effect on price, but subsequent entrants dramatically reduce the average relative price." *Id.* at 5. More precisely, "the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price. * * * For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower."[6]

If generics are shut out from marketing in certain States—the lower court's "solution" to the federal-state conflict at issue here—these savings will dwindle, threatening generic drug makers' livelihoods and harming the consumers they serve. Fewer competitors in the market means higher prices. At a minimum, the ruling below threatens to work fundamental changes in the way generics do business—including by multiplying their costs—to the ultimate detriment of consumers and the nation's health care system. These results would be squarely at odds with the purpose of the Hatch-Waxman Act.

That Act is "the supreme Law of the Land," "any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. But where federal law is designed to foster inexpensive, widely available generic drugs, state regula-

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[6] FDA, *Generic Competition and Drug Prices*, available at: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

tion —in the form of prohibition or otherwise—would result in increased prices, decreased availability of generics as manufacturers exit the market, or both.

Even indulging the assumption that allowing juries to impose state tort liability might make drugs safer (which is doubtful), Congress has already struck a balance between safety and cost. And where federal law reconciles competing objectives, "that is not a judgment the States may second-guess." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989). Rather, state regulation "must yield to the extent that it clashes with the balance struck by Congress." *Ibid.*; accord *Geier*, 529 U.S. at 874-881 (state tort law is preempted insofar as it balances competing policy objectives—including issues of cost and safety—differently from federal law).

2. Nor can a role for state regulation be preserved on the theory that state tort law is merely providing "parallel" enforcement of federal drug safety requirements. In *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005), this Court held that state courts may enforce federal requirements for pesticide labels. 544 U.S. at 451-452. Although the express preemption provision at issue there barred States from imposing "any requirements for labeling or packaging in addition to or different from those required" by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") (*id.* at 443 (citation omitted)), the Court determined that this did not preempt state law *remedies* for violations of federal standards. Under the statutory framework here, however, there is no place for "parallel requirements." *Id.* at 447.

First, in cases such as this, state and federal law impose different standards. Unlike the state law ap-

plied below, federal law does not require that generic drugs satisfy a "risk-benefit analysis" (Pet. App. 10a); it requires that generics be "the same as" their brand-name counterparts. Thus, state law is not enforcing applicable federal law at all; it is at best *extending* federal law such that generic drug makers are subject to a pair of mutually exclusive drug-design standards: As the First Circuit acknowledged, generics "cannot legally" differ from their brand counterparts. *Ibid.* Yet the court affirmed a jury verdict imposing liability based on petitioner's failure to do precisely that—depart from the brand-name design.

Second, and in any event, the authority and discretion to take action against a manufacturer for noncompliance with the FDCA rests "exclusively [with] the Federal Government." *Buckman*, 531 U.S. at 352. As this Court explained in *Buckman*, the FDA may well prefer a more "measured response" than that of a lay jury hearing one case in isolation. *Id.* at 349. Further, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" *Id.* at 349 n.4 (quoting 21 U.S.C. § 337(a)). The same is equally true of any federal requirement that state law might purport to enforce via drug design-defect liability—including prohibitions on "misbranding" (*e.g.*, 21 U.S.C. § 352(j)), the safety and efficacy requirements that must be met for *NDA* approval (*id.* § 355(d)(1)), and post-approval reporting requirements (21 C.F.R. § 314.98)—all of which are part of the FDCA and subject to § 337(a).

Notably, § 337(b)(1) provides a limited exception to § 337(a)'s rule that only the Federal Government may enforce the FDCA: A State may bring suit to enforce or restrain violations of certain federal rules with respect to "food" within its borders. 21 U.S.C. § 337(b)(1). This exception does not apply to drugs. And even with respect to food, a State may proceed *only* after giving notice to the Secretary of Health and Human Services, and *only* if the Secretary has not herself taken action. See *id.* § 337(b)(2).

It is thus by design that consumers claiming harm from FDA-approved drugs have no federal cause of action. Cf. *Shady Grove Orthopedic Assocs., P.A.* v. *Allstate Ins. Co.*, 130 S. Ct. 1431, 1438 (2010) ("The fact that Congress has created specific exceptions to [a rule] hardly proves that the [r]ule does not apply generally. In fact, it proves the opposite"; if the rule did not apply generally, "the statutory exceptions would be unnecessary"); *Block* v. *Community Nutrition Inst.*, 467 U.S. 340, 349 (1984) ("when a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded").[7] Instead, the FDA has several means of re-

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[7] This Court recently rejected a similar argument in *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians* v. *Patchak*, 132 S. Ct. 2199 (2012), because the plaintiff there (in suing under the Administrative Procedure Act) was "bringing a different claim, seeking different relief, from the kind" that was "barred" (under the Quiet Title Act). See *id.* at 2208-2209. The premise of any "parallel requirements" defense of the design-defect claim here, however, has to be that it is the same claim (for violation

gulating the conduct of generic manufacturers and their products, including withdrawal of approval;[8] suspension of approval;[9] injunctions;[10] criminal penalties;[11] seizure;[12] and enforcement proceedings.[13] The FDCA also preserves the FDA's discretion to take less stringent action where appropriate.[14]

The availability of this range of regulatory options "is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349. And when it determines that the FDCA has been violated, the FDA has "complete discretion" to pursue the remedy that, in its judgment, best fits the violation. *Heckler* v. *Chaney*, 470 U.S. 821, 835 (1985).

State tort law, by contrast, operates in a vacuum, divorced from any obligation or incentive to balance the goal of product safety against other worthy (and sometimes competing) policy objectives—such as patients' interest in access to life-saving medicines with potentially significant side effects, and the financial interest of consumers or our health care system as a

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of federal safety standards), seeking the same relief (a safer drug design).

[8] 21 U.S.C. § 355(e); 21 C.F.R. §§ 314.150, 314.151.

[9] 21 C.F.R. § 314.153.

[10] 21 U.S.C. § 332(a).

[11] *Id.* § 333(a).

[12] *Id.* § 334(a).

[13] *Id.* § 337(a).

[14] *Id.* §§ 336, 375(b).

whole in the billions of dollars of savings provided by widely available, low-cost generic drugs. Even if state and federal law share the same ultimate goal, "[t]he fact of a common end hardly neutralizes conflicting means." *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363, 379 (2000). Accordingly, state law is still preempted if it "interferes with the methods by which the federal statute was designed to reach this goal." *Int'l Paper Co.* v. *Ouellette*, 479 U.S. 481, 494 (1987); see also *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959) ("[S]ince remedies form an ingredient of any integrated scheme of regulation, to allow the State to grant a remedy here which has been withheld from the [federal agency] only accentuates the danger of conflict.").

Here, state common law regulation would impose substantial costs on generic manufacturers. These costs cannot be brushed aside as extra incentive to comply with federal law; instead, they "would exert an extraneous pull on the scheme established by Congress," and "[are] therefore pre-empted." *Buckman*, 531 U.S. at 353.

B. This Court's precedents foreclose any argument that jury verdicts are just a cost of doing business.

It is no answer to say that any conflict here can be avoided by the generic continuing to sell its product while paying state-court judgments. Such an argument is inconsistent not only with *Mensing*, but also with a long line of this Court's precedent, and with the Supremacy Clause—neither of which draws any distinction between state positive or regulatory law and state common law.

Mensing easily could have avoided any finding of a conflict between state and federal law by holding that state-law failure-to-warn judgments were simply a cost of doing business. Not surprisingly, however, the parties there did not even "dispute that * * * state law required the Manufacturers to use a different, safer label." 131 S. Ct. at 2574. As this Court held in *Riegel*, "common law liability is premised on the existence of a legal duty, and a tort judgment therefore establishes that the defendant has violated a state-law obligation. And while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy." 552 U.S. at 324 (internal citation and quotation marks omitted).

Riegel is but one decision in a long line of precedents to the same effect. The leading case is *Garmon*, which over 50 years ago recognized that "regulation can be as effectively exerted through an award of damages as through some form of preventive relief." 359 U.S. at 247. And just last Term, this Court reiterated that "[t]he obligation to pay compensation" is "a potent method of governing conduct and controlling policy." *Kurns*, 132 S. Ct. at 1269 (quoting *Garmon*).

In keeping with these authorities, federal preemption of "state tort suit[s]" is a settled component of "ordinary conflict preemption principles." *Williamson* v. *Mazda Motor of Am., Inc.*, 131 S. Ct. 1131, 1136 (2011) (citing *Cipollone* and *Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141 (1982)); see also *Erie R.R. Co.* v. *Tompkins*, 304 U.S. 64, 78 (1938) ("whether the law of the State shall be declared by its Legislature in a statute or by its highest court in a decision is not a matter of federal concern"); *Shelley* v. *Kraemer*, 334 U.S. 1, 17 n.19 (1948) ("common-law rules enunciated by state courts in judicial opinions

are to be regarded as a part of the law of the State"). And, of course, the Supremacy Clause itself draws no distinction between state positive and common law: It preempts "any Thing in the Constitution or Laws of any State" that is "Contrary" to federal law. U.S. Const., Art. VI, cl. 2.

The only case in which this Court has even arguably wavered from this rule is *Bates*, where Justice Stevens' opinion for the Court observed that "[a] requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action." 554 U.S. at 445 (internal citation omitted). But the Court there was interpreting FIFRA's express preemption provision—which preempted "any requirements for labeling or packaging in addition to or different from those required" by FIFRA itself—and its distinction between "jury verdicts" and "common-law duties" rested on the "best reading" of "requirement" in that provision. *Id.* at 443. As *Riegel* later reiterated: "Absent other indication, reference to a State's 'requirements' includes its common law duties." 552 U.S. at 324; cf. *Cipollone*, 505 U.S. at 521 (plurality per Stevens, J.).

Indeed, if *Bates* were read to suggest that complying with a state "common-law duty" is obligatory, but complying with a jury verdict that implements that duty is "optional," it would run headlong into the precedents discussed above, which both pre- and post-date *Bates*. It would also violate a basic premise of the jury system—that juries follow the law. If a jury's tort verdict did not implement an applicable

common-law duty, any resulting award of damages would be lawless. *Riegel*, 552 U.S. at 324 ("common law liability is 'premised on the existence of a legal duty,' and a tort judgment therefore establishes that the defendant has violated a state-law obligation").

Presumably that is why *Geier* v. *American Honda Motor Corp.*, 529 U.S. 861 (2000), emphasized that "[t]his Court's pre-emption cases do not ordinarily turn on such compliance-related considerations as whether a private party in practice would ignore state legal obligations—paying, say, a fine instead—or how likely it is that state law actually would be enforced. Rather, this Court's pre-emption cases ordinarily *assume* compliance with the state-law duty in question." *Id.* at 882. Likewise, *Riegel* did not even *question* whether a jury verdict must be obeyed, but instead held that it was "implausible" that the statute there "was meant to 'grant greater power * * * to a single state jury than to state officials acting through state administrative or legislative lawmaking processes.'" 552 U.S. at 325 (quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 504 (1996)). So too here.

C. State tort claims challenging the design of complex products that are heavily regulated by the federal government are especially unsuitable for juries and especially suitable for preemption.

In addition, for complex pharmaceutical products that are sold nationwide and heavily regulated by the FDA, it is especially appropriate for Congress to bar state law—and certainly juries—from regulating product design.

1. For complex products that are mass-produced, easily transported, and heavily regulated at the federal level, a patchwork quilt of additional state regu-

lation is quite problematic. It raises the costs of compliance and makes it difficult for consumers to discern what is safe and what is not.[15] Likewise, the national economy is weighed down if manufacturers of national products that are already closely controlled by federal rules must submit to "diverse, nonuniform, and confusing * * * regulations." *Cipollone*, 505 U.S. at 514.

This is particularly true where the product is as sophisticated as the chemical drug compounds at issue here. If there is a problem with the design of a pharmaceutical, it cannot be fixed by adding, say, a simple safety guard or turn-off switch. The costs of re-engineering drugs is astronomical—which is one reason why Hatch-Waxman prescribes that generic drugs simply be "the same as" the brand. But while the First Circuit seemed to grasp the impossibility of changing a drug's design (Pet. App. 10a), the court's cure—taking the product off the market entirely—was worse than the alleged disease. Rather than allowing juries to create a patchwork quilt of standards (which would have been forbidden as well), the deci-

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[15] See, *e.g.*, James A. Henderson, Jr., *Judicial Review of Manufacturer's Conscious Design Choices: The Limits of Adjudication*, 73 Colum. L. Rev. 1531, 1576 (1973) ("the legislative and administrative processes are institutionally suited" to "establishment of specific design standards."); Michael W. McConnell, *A Choice-of-Law Approach to Products-Liability Reform*, in New Directions in Liability Law, 37 Proceedings of the Acad. of Political Science 90, 91 (1988) ("[s]ince most products are made in one state and used in another, at least two states are usually involved," and "they will not all be able to get their way when their laws differ").

sion below would allow juries to create a patchwork quilt of *prohibitions*.

Again, if "[t]he obligation to pay compensation" is "a potent method of governing conduct" (*Kurns*, 132 S. Ct. at 1269 (citation omitted)), it is likewise potent to drive a product out of a state market altogether. Unlike brand-name drugs, generics typically have a thin profit margin—which means that a single jury verdict on the order of the one here ($21 million, for a single plaintiff) may demand abandoning a given market. Further, being shut out of entire markets can be a company killer, particularly for small companies. In *Buckman*, the Court recognized that the "fear" of "expos[ing] the manufacturer * * * to unpredictable civil liability" might "discourage [applicants] from seeking § 510(k) approval of devices." 531 U.S. at 350. So too may the prospect of being forced to drop products entirely in various States deter the development of needed low-cost generic medicines.

Allowing design-defect claims would also permit juries in 50 different States to reach judgments that differ from the FDA's—and from each other's. As the Court recognized in *Garner* v. *Teamsters*, 346 U.S. 485, 490-491 (1953), "[a] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law." Citing this danger, *Buckman* explained that allowing liability under "50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress." 531 U.S. at 350. The same is true of the design-defect claims here.

Indeed, because drugs cross state lines, the ruling below effectively allows the most pro-ban State to set

policy for the whole nation, undermining the Act's goal of quickly getting generic drugs to the national market. But "one State's power to impose burdens on the interstate market" is "constrained by the need to respect the interests of other States." *BMW*, 517 U.S. at 571. And where, as here, "[t]he subject-matter * * * peculiarly * * * calls for uniform law," States should not be permitted to "supplement" federal mandates, much less overrule them outright. *Penn. R.R.* v. *Public Serv. Comm'n*, 250 U.S. 566, 569 (1919). Yet that is exactly what the decision below accomplishes in allowing States to blacklist products that the FDA, after extensive study, has deemed safe and effective.

In fact, a generic company whose drug product is banned by a given State may well lose its ability to sell that product in any State. In the experience of these *amici*, national retailers facing a patchwork of state rules concerning a given drug—some permitting the drug to be sold, others prohibiting it—may simply refuse to sell a drug at all, rather than keep track of States and stores where the drug may be shipped and those where it may not. And for smaller generic manufacturers, the loss of an entire product can put the company under.

2. As this Court has recently emphasized in the context of medical device liability, these problems are further exacerbated where, as here, a ruling authorizes a ban to be imposed "by juries." *Riegel*, 552 U.S. at 325. "A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm?" *Ibid.* Juries, howev-

er, simply are not constituted or equipped to regulate products such as those at issue here. "A jury * * * sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court." *Ibid.* Similarly, "[i]t would be difficult for a jury focused on a single case to take into account 'the cumulative, systemic effects' of a series of verdicts. In contrast, the FDA possesses a broader perspective." *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 797 (8th Cir. 2001) (internal citation omitted) (quoting Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 Geo. L.J. 2167, 2175 (2000)).

In enacting Hatch-Waxman, Congress acted to replace a patchwork of state tort standards with a uniform, feasible, safe, and economically sound set of rules established by an expert agency and imposed on a prospective basis. It is the FDA (not juries) that is charged with determining whether a product's benefits outweigh its risks—and hence whether it is safe and effective. Again, the involvement of juries is "not required or even suggested" by the Act, and the courts should not "turn somersaults" to create it. *Riegel*, 552 U.S. at 325. Particularly in light of *Mensing*, however, turning somersaults is an apt description of the approach taken below.

States generally may not provide causes of action that fail to give effect to federal administrative decisions that have neither been rescinded by the agency nor set aside by the federal courts. *Arkansas La. Gas Co.* v. *Hall*, 453 U.S. 571 (1981); *Chicago & North Western Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981). And yet the claim here proceeded on the theory that respondent should receive damages as

if marketing a drug approved by the FDA as "safe and effective" were unlawful. See Pet. App. 10a. Reversal is warranted to prevent this type of admitted second-guessing of the expert agency, contrary to the statutory scheme, as to a species of tort claim especially well-suited for uniform federal regulation.

III. Taken to its logical conclusion, the First Circuit's rationale would eliminate all application of the doctrine of conflict preemption to claims against manufacturers in federally regulated industries.

Finally, beyond being untenable in the particular context of Hatch-Waxman and generic drugs, the First Circuit's decision would effectively destroy the doctrine of conflict preemption as applied to federally regulated industries.

According to the First Circuit, a generic "certainly can choose not to make the drug at all; and the FDCA might permit states to tell [petitioner] it ought not be doing so if risk-benefit analysis weighs against the drug." Pet. App. 10a. But just this kind of counterfactual argument was rejected in *Mensing*. And if it were the law, a host of this Court's preemption decisions would have come out the other way.

The plaintiff in *Mensing* contended that, "if the Manufacturers had asked the FDA for help in changing the corresponding brand-name label, they might eventually have been able to accomplish under federal law what state law requires." 131 S. Ct. at 2578. That is, if the Manufacturers had asked, "and if the FDA decided" to help, "and if the FDA undertook negotiations," "and if adequate label changes were decided on and implemented, then the Manufacturers

would have started a Mouse Trap game that eventually led to a better label." *Ibid.*

This Court refused to accept that "conflict preemption should take into account these possible actions." *Ibid.* Instead, it held that "[t]he question for 'impossibility' is *whether the party could independently do under federal law what state law requires of it.*" *Id.* at 2579 (emphasis added). In other words, the law of preemption assumes stasis: The regulated party keeps producing the same product; and the federal government keeps enforcing the same law.

To assume away one of these fixed assumptions is to render any resulting harmony in the law illusory. As the Court put it in *Mensing*: "If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. We do not read the Supremacy Clause to permit an approach to preemption that renders conflict preemption all but meaningless." 131 S. Ct. at 2579. Similarly, the Court in *Geier* rejected an attempt to show the lack of a conflict based on the notion that the manufacturer could have complied with state law by selling "a *different* kind of" product. 529 U.S. at 882 (emphasis in original).

Such conjectures contain no limiting principle. No matter how clear an agency tries to be—even forbidding requests for rule changes themselves—the plaintiff could always say, "But 'they did not even try to start the process'" that might have alleviated the conflict. 131 S. Ct. at 2579. There would be no rational basis for preventing this infinite regression of one-upsmanship. See *Mensing* Oral Arg. Tr. 38:8-15

(Alito, J.) ("[S]uppose that the FDA issued a rule that says a generic drug manufacturer has no obligation to request a change in labeling. Could a generic drug manufacturer be held liable on a failure to warn claim on the theory that it could have lobbied the FDA to change the rule that says that the generic drug manufacturer has no obligation to ask for a change in labeling?").

The First Circuit took exactly the path forbidden in *Mensing*. To prevent federal and state law from conflicting, it relied on conjectures of the worst kind: assuming the generic abandoned its product. Pet. App. 10a. Insofar as abandoning the product is *always* an option, that view leaves conflict preemption without any force. After all, "if federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior." *Wyeth*, 555 U.S. at 590 (Thomas, J., concurring).

This holds true across federally regulated industries. Whether it is the automobile industry (*Geier*), the cigarette industry (*Cipollone*), the generic drug industry (*Mensing*), or others, it is untenable to say that the solution to federal-state conflicts is simply to stop making products. And if *Mensing* can be distinguished in this way, then so too can *Geier*, *Cipollone*, and like cases. Affirmance of the decision below cannot be reconciled with these precedents, as the response to every defense of conflict preemption involving a federally regulated product would be simple: Pull the product from the market. For this reason too, the decision below demands reversal.

* * * * *

The decision below should be reversed for at least three reasons. *First*, the First Circuit's distinction between design-defect and failure-to-warn claims is foreclosed by the Hatch-Waxman Act, logic, and binding precedent. *Second*, if allowed to stand, the decision below would upset the basic economic structure of the generic drug industry, and impose burdens on generic drug makers and consumers that fly in the face of Hatch-Waxman's core objectives. Indeed, the whole point of the Hatch-Waxman framework is to increase the availability of low-cost generic drugs—a goal circumvented if generic manufacturers can "comply" with conflicting state and federal drug design requirements only by taking their products off the market. *Third*, the stop-selling rationale would destroy the doctrine of conflict preemption as applied to manufacturers of federally regulated products.

If federal supremacy is to mean anything, state courts must not be permitted to ban complex pharmaceutical products whose compliance with the mandates of federal law brings them into conflict with state standards.

CONCLUSION

For the foregoing reasons, the decision below should be reversed.

Respectfully submitted.

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In The Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,

Petitioner,

v.

KAREN L BARTLETT,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF FOR DR. JOHN T. SCHULZ, III AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICUS CURIAE* [1]

Amicus curiae Dr. John T. Schulz. III is a surgeon specializing in burn trauma and critical care and the head of the burn unit at Bridgeport Hospital in Connecticut, which is part of the Yale-New Haven health system and associated with Yale Medical School. He has a Ph.D. from Harvard in Biochemistry, a medical degree from Yale, is on the faculty of the Yale School of Medicine, and has taught at Harvard Medical School. In addition to his surgical practice, Dr. Schulz is a research scientist who has conducted clinical and basic research in a number of areas, including research on toxic epidermal necrolysis, one of the conditions caused by sulindac and suffered by Respondent Karen Bartlett. He has researched, published on, and treated patients with TEN for over 14 years.

Dr. Schulz was one of Respondent's treating physicians at the Mass. General Hospital burn unit. He testified at the trial below regarding the nature and extent of Respondent's injuries and his treatment of Respondent.

Dr. Schulz is interested in this case because of his personal experience with the harm that sulindac caused to one of his patients, his extensive knowledge of the dangers of sulindac and of Stevens-Johnson

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[1] No counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *amicus* or his counsel, make a monetary contribution intended to fund the preparation or submission of this brief. This brief is submitted pursuant to the blanket consent letters from all parties, on file with this Court.

syndrome and toxic epidermal necrolysis in general, and his concern that FDA is not capable of acting as the sole bulwark against the dangers of drugs like sulindac.

SUMMARY OF ARGUMENT

1. The regulatory history of sulindac – a non-steroidal anti-inflammatory drug ("NSAID") – is an unfortunate example of how FDA is not capable of being the sole guardian of public safety in connection with drugs. First cleared for sale in 1978, previously unappreciated threats from sulindac emerged in subsequent decades, including the severe, though infrequent and unpredictable, threat of Stevens-Johnson syndrome and toxic epidermal necrolysis ("SJS/TEN"). Almost all NSAIDs carry some risk of SJS/TEN, but the risk from sulindac was higher than all other NSAIDs on the market from 1980 through 1997. Although FDA eventually required the labels of NSAIDs to carry warnings of this threat, it did not request sulindac's removal from the market or withdraw its consent for the sale of the drug.

In 2005, by contrast, FDA asked that Bextra – a then relatively new COX-2 selective NSAID – to be withdrawn from the market based on 7 reported deaths from SJS/TEN, a supposedly higher reporting rate of SJS/TEN for Bextra than for other COX-2 selective NSAIDs, and the lack of unique medical advantage for Bextra compared to other NSAIDs. At the same time, however, FDA essentially ignored equally or more damning evidence against sulindac. In fact, sulindac was associated with significantly more deaths from SJS/TEN than Bextra, had the

highest adjusted reporting rate of SJS/TEN compared to any other NSAID between 1980 and 1997, had a higher death rate per reported case than Bextra, and there was more compelling evidence of a causal link between sulindac and SJS/TEN than there was for Bextra. Sulindac thus raised safety concerns comparable to or greater than Bextra and similarly had no offsetting medical advantages relative to the numerous other NSAIDs on the market.

FDA's inconsistent treatment of the serious dangers of Bextra and sulindac illustrates that FDA is not an omniscient and unerring arbiter of drug safety, as Petitioner and its *amici* seem to suggest. Rather, it is a body with limited time, resources, and expertise that is not capable of being the exclusive judge of drug safety in the United States. While it performs an important function as a first-line safety hurdle and a last-ditch safety backstop, it cannot replace the decentralized operation of state common law as a means of addressing drug safety issues above the inconsistently implemented federal minimum standards.

2. In addition to being *incapable* of performing the role of an exclusive and centralized arbiter of drug safety or hazard, FDA was never designed nor intended to assume such a role. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 310, *et seq.*, FDA approval is not the *final* say on whether a drug is safe, and it does not confer a *right* to sell any particular drug throughout the United States. Rather, it is only the *first* determination regarding drug safety and a condition precedent to avoiding a preemptive congressional bar on the sale

of a drug. And there certainly is nothing in the FDCA giving FDA authority to decide how to allocate responsibility for the risks and consequences of various drugs that have overcome the minimum federal hurdle and made it onto the market. It is perfectly consistent with the role of FDA and its actual operations in this area for it to determine that a drug may be safe enough to avoid a preemptive congressional bar on its sale, yet for various States to determine that the remaining dangers of the drug are such that responsibility for the risks from its use should be allocated to the manufacturer. Such potential state-law liability does not second-guess FDA's enforcement of federal minimum safety standards; it addresses a wholly separate question that FDA lacks authority to answer.

2. The Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), likewise does far less than Petitioner and its *amici* suggest. To start with, this case has nothing to do with any differences between generic and brand-name manufacturers. Strict liability would apply equally to *any* manufacturer of sulindac, and the so-called "sameness" requirement imposes no unique burden on generic manufactures in this context. Furthermore, the Act does not grant generics unique legal and economic immunity in the market. Rather, it merely provides expedited and simplified means for additional companies seeking to sell generic versions of drugs already on the market to clear the FDA-approval hurdle. The Act does so by lowering unnecessary barriers to entry if a drug is the same as one already on the market, thus allowing for increased competition on equal footing with the brand-

name manufacturers that could recoup their initial FDA approval costs during their period of patent exclusivity.

Contrary to Petitioner's repeated suggestion, the Hatch-Waxman Act does not *require* any manufacturer to produce a drug that is the "same" as an existing drug on the market. "Sameness" is merely a condition precedent to the simplified procedures designed to put generics on equal competitive footing with their branded alternatives. Hatch-Waxman never sought to insulate them from *all* state-law liability, much less from the "same" strict liability that would be faced by their branded competitors. If any given drug is deemed unreasonably dangerous and hence subject to strict liability, that determination would apply equally to the branded and generic versions of the drug (assuming the generics were, in fact, the "same" as the branded version in all material respects). Liability such as found in this case thus puts no unique burdens on generics, puts them to the exact same choices as their branded competitors, and thus is entirely consistent with the purposes and terms of the Hatch-Waxman Act.

ARGUMENT

I. FDA's Failure Concerning the Dangers of Sulindac Illustrates the Inappropriateness of Enthroning FDA as the Exclusive Arbiter of Drug Safety.

Sulindac is a non-steroidal anti-inflammatory drug ("NSAID") used to relieve pain resulting from a variety of conditions. [JA553] It was first approved by FDA for sale in 1978. After the patent on Sulindac

expired, it was approved for sale in generic form in 1988, and approved for sale by Petitioner in 1991. [CAA2169]

Although pre-marketing clinical trials of sulindac "indicated the occurrence of only relatively mild adverse effects, * * * during postmarketing clinical experience, reports began to accumulate describing serious adverse reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, hepatotoxicity, pancreatitis, granulocytopenia, aplastic anemia, and thrombocytopenia." Glen D. Park, Reynold Spector, Thomas Headstream, and Mark Goldberg, *Serious Adverse Reactions Associated with Sulindac*, 142 ARCH. INTERN. MED. 1292 (1982). [JA596] While those reports influenced sulindac's label, which by 2002 warned that adverse "[d]ermatologic" reactions including TEN and SJS, along with other "[h]ypersensitivity reactions," were "potentially fatal" [JA554], the drug remained on the market.

FDA's failure to pull sulindac's approval for marketing is particularly surprising given that medical reports throughout the 1980s and 1990s regularly listed sulindac as a leading cause of SJS/TEN.[2] In fact, from 1980 to 1997, sulindac had more reported cases of SJS/TEN in FDA's reporting system than

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[2] *See, e.g.*, Michael Bigby, Robert S. Stern, and Kenneth A. Arndt, *Allergic Cutaneous Reactions to Drugs*, 16 PRIMARY CARE 713, 719 (1989) ("Two large series of cases [of TEN] have been reported. The drugs most commonly implicated are the NSAIDs (especially phenylbutazone, oxyphenbutazone, sulindac, and piroxicam), antibiotics (especially trimethoprim-sulfamethoxazole), the barbiturates, phenytoin, and allopurinol."). [JA613]

any other NSAID. Robert S. Stern, Maja Mockenhaupt, Judith Parsells, and David Kaufman, *Analysis and Prevention of Data that assess the risk of Stevens-Johnson Syndrome and toxic epidermal necrolysis associated with nonsteroidal anti-inflamatory drugs* 10-11 (Final Report to Pharmacia, Inc., Oct. 2001) ("The NSAIDs with the most reports coded as SJS or TEN, (sulindac (89 reports)) ranked fifth among all drugs on the basis of total reports."). [JA627-28] By 2004, the number of reports for sulindac had grown to 134. [Pet. App. 44a (district court discussion of the testimony)]

Not only did sulindac have the highest total number of reports among the NSAIDs, it also had the highest adjusted rate of reports and, along with the next closest NSAID, had "*significantly and substantially higher rates* of reports [of] SJS/TEN reactions relative to office visits with a prescription than other NSAIDs." *Id.* at 12 (emphasis added). [JA629]; *see also* Maja Mockenhaupt, Judith Parsells Kelly, David Kaufman, Robert S. Stern, and the SCAR Study Group, *The Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis Associated with Nonsteroidal Anti-inflammatory Drugs: A Multinational Perspective*, 30 J. RHEUMATOLOGY 2234, 2237 (2003) (sulindac in the U.S. had reporting rates comparable to the high-risk NSAID piroxicam, used widely in Europe).

In addition to having a high rate of reported SJS/TEN reactions, sulindac may create a risk of more severe reactions because it has a long half-life in the body. *See* Pierre E. Wolkenstein, Jean C. Roujeau, Jean Revus, Drug-Induced Toxic Epidermal

Necrolysis, 16 CLINICS IN DERMATOLOGY 399, 403 (1998) ("NSAIDs with long half-lives (pyrazolones, oxicams, fenbufen, sulindac) are suspected to have higher risks [of TEN].") [JA623]; Tr. Testimony (Dr. Tackett) (longer half-life drugs have a higher risk of producing SJS/TEN) [JA480]. Patients "exposed to causative drugs with long half-lives had an increased risk of dying." Ignacio Garcia-Doval, Laurence LeCleach, Helene Bocquet, Xose-LuisOtero, Jean-Claude Roujeau, *Toxic epidermal necrolysis and Stevens-Johnson syndrome: does early withdrawal of causative drugs decrease the risk of death?* 136 ARCH. DERMATOL. 323 (2000).

That increased risk of death is borne out with sulindac. During the 1980s alone, there were at least 13 deaths reported in the literature for sulindac-associated SJS/TEN. *See* Kristina E. Ward, Raoul Archambault, Tracey L. Mersfelder, *Severe Adverse Skin Reactions to Nonsteroidal Antiinflammatory Drugs: A Review of the Literature*, 67 AM. J. HEALTH SYS. PHARM. 206 (2010) (reviewing articles from the 1980s reporting deaths from sulindac-associated SJS/TEN) (available at http://www.medscape.com/viewarticle/717043_4). Through 1997, reported deaths from sulindac-associated SJS/TEN totaled at least 38, with 32 in the United States. Tr. Testimony (Dr. Salisbury) [JA425]; *see also* Tr. Testimony (Dr. Tackett) (at least 39 reported deaths from sulindac-associated SJS/TEN) [JA 466]; Pet. App. 44a-45a (39 deaths out of 134 reported cases through 2004).

And if the reported incidents of, and deaths from, sulindac-associated SJS/TEN were not troubling

enough, it is well-known that drug-related SJS/TEN is notoriously under-reported, meaning that the reported cases actually vastly underestimate the true rate of drug-associated SJS/TEN. *See* Mittman, N., *et al.*, *Evaluation of the Extent of Under-Reporting of Serious Adverse Drug Reactions, The Case of Toxic Epidermal Necrolysis*, 27 DRUG SAFETY 477 (2004) (study in Canada concluding that only 4% to 10% of TEN cases are reported); Lois La Grenade, Lauren Lee, Joyce Weaver, Renan Bonnel, Claudia Karwoski, Laura Governale and Allen Brinker, *Comparison of Reporting of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Association with Selective COX-2 Inhibitors*, 28 DRUG SAFETY 917, 922 (2005) (because of substantial under-reporting, "reporting rates cannot be equated with incidence rates") [JA637]. In fact, *amicus* Dr. Schulz's own extensive experience with SJS/TEN cases at burn centers, and his knowledge of their general lack of reporting of such cases to FDA, suggests that FDA's database likely contains only 5%, or one-twentieth, of the actual cases of drug-associated SJS/TEN.

FDA's failure to recognize and respond adequately to the dangers from sulindac is particularly mystifying given its relatively timely reaction to the SJS/TEN dangers from Bextra – a more recent COX-2 selective NSAID. As part of its review of the cardiovascular risks of the newer COX-2 selective NSAIDs Celebrex, Vioxx, and Bextra, an FDA Committee also reviewed reports of SJS/TEN associated with Bextra. As a result of that review, the Committee concluded that "the overall risk versus benefit profile for Bextra is unfavorable at this time" and recommended "that

Bextra be withdrawn from the U.S. market." Memorandum, Apr. 6, 2005 ("FDA Memo."). [JA588] The Committee based this recommendation on its conclusion that although it found "no data showing that Bextra is worse than other NSAIDs with regard to CV risk," and despite the boxed warning for Bextra regarding SJS/TEN, the FDA had "received 7 spontaneous reports of deaths from these reactions" and that the "reporting rate for these serious skin reactions appears to be greater for Bextra than other COX-2 selective agents." *Id.* [JA589] The Committee found particularly notable that "the risk of these serious skin reactions in individual patients is unpredictable, * * * which makes risk management efforts difficult." *Id.* [JA589]

Based on such heightened risks, and the lack of evidence that Bextra had any advantage over other NSAIDs in terms of "a GI safety benefit, better efficacy compared to other products, or efficacy in a setting of patients who are refractory to treatment with other products," there was nothing to offset the heightened risk and thus withdrawal from the market was appropriate. *Id.* [JA589]

Comparing sulindac to Bextra makes the disparate treatment of the two drugs more than surprising. Sulindac was associated with a higher number of reported incidents of SJS/TEN than was Bextra – at least 134 versus 63. Sulindac was associated with a higher number of *fatalities* from SJS/TEN than was Bextra – at least 13 during only a fraction of its time on the market, and 39 deaths through the early 2000s, versus 7 for Bextra. Sulindac had the highest adjusted reporting rate for SJS/TEN of *any* NSAID on

the market between 1980 and 1997. Stern, *et al.*, Final Report to Pharmacia, *supra*, at 12 [JA629].[3] Sulindac had a higher fatality rate per reported incident than Bextra (39/134 versus 7/63, respectively), suggesting more serious and dangerous reactions from sulindac. And the evidence of a causal relationship between sulindac and SJS/TEN was stronger than it was for Bextra: while the reported Bextra incidents all involved a correlation between use and SJS/TEN, for sulindac there were reported cases in which a re-challenge with the drug led to a recurrence of SJS. Tr. Testimony (Dr. Tackett) (noting positive rechallenges in the sulindac literature) [JA480].

Indeed, the testimony at trial was "that sulindac had * * * a safety profile similar to other drugs deemed dangerous enough to have been withdrawn from the market," including Bextra. Pet. App. 4a-5a; *see also* Pet. App. 39a-58a, 65a (district court discussing evidence on risks and benefits; discussing expert

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[3] Although Bextra's SJS/TEN reports occurred over a shorter time period than did sulindac's reports, Bextra's usage rate was considerably higher and occurred at a time when awareness of the link between drugs and SJS/TEN had improved and reporting rates in general were higher. *See* Stern, *et al.*, Final Report to Pharmacia, *supra*, at 12 [JA629]. Indeed, that sulindac's reports were as high as they were, given the timeframe of its introduction, its lower usage rate, and the under-reporting of SJS/TEN drug reactions in general, makes it all the more remarkable that those high numbers did not trigger significant red-flags at FDA.

testimony that sulindac carried higher risk and no greater benefits than other NSAIDs).

Petitioner's suggestion, at 19, that FDA's review of Bextra, its subsequent strengthening of the warnings for other NSAIDs, and its failure to also remove sulindac from the market somehow constitute an affirmative endorsement of sulindac's safety and net benefit seriously misreads FDA's limited actions and information. There is no indication that FDA actually reviewed evidence regarding the SJS/TEN risk from sulindac and its review of Bextra was limited to a comparison to other COX-2 selective NSAIDs, not the non-selective NSAIDs such as sulindac. *See* Resp. Br. 6-7, 52-53; FDA Memo. (comparing risk to other COX-2 selective agents) [JA589]; Tr. Testimony (FDA lacked study regarding sulindac risks) [JA429-31]. Any further suggestion that FDA specifically endorsed sulindac after a "comprehensive analysis," Generic Pharm. Ass'n Amicus Br. 28, thus seems palpably false, is not backed by any evidence of such a review, and, if true, merely shows that the review was woefully deficient in that FDA did not even discuss the substantial red-flags related to sulindac. In short, nothing FDA did could possibly be deemed a considered decision that sulindac *should* stay on the market, that its cost-benefit ratio was favorable, or that state-law decisions to the contrary should be preempted.

What is actually more interesting and relevant about FDA's review of Bextra is that its reasons for why Bextra lacks any unique therapeutic benefit to offset its greater risks all apply equally to sulindac. *See* FDA Memo. (no data to distinguish NSAIDs on

other risks or unique therapeutic benefits) [JA577-79]. Furthermore, FDA found that Bextra was unfit for marketing notwithstanding that it already had a black-box warning –the strongest type available – for SJS/TEN reactions. *Id.* [JA579-81]. That treatment demonstrates that unreasonable danger can exist regardless of available warnings or even in the face of the maximum possible warning. Such a warning could not save Bextra and equally could not rehabilitate sulindac. The FDA's treatment of Bextra thus flatly contradicts Petitioner's attempts to frame this case as implicitly involving a failure-to-warn claim.

FDA's review of sulindac and related drugs illustrates that FDA is not remotely capable of adequately policing the all drugs on the market, or of responding to emerging threats in a reliable and consistent manner. Indeed, FDA's failure regarding sulindac should come as no surprise to this Court, which has already recognized FDA's "limited resources to monitor the 11,000 drugs on the market." *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009). Given such limitations, this Court should decline Petitioner's efforts to characterize FDA as more than a limited gatekeeper or to elevate it to the role of exclusive and omnipotent arbiter of all matters drug-related. FDA is not fit for that role and was not intended for that role.

II. FDA Is Not Intended To Be the Sole Bulwark Against the Dangers of Prescription Drugs Sold by Branded or Generic Manufacturers.

A. The FDCA Only Empowers FDA to Enforce Federal Minimum Safety Standards, Not to Impose Preemptive Maximum Safety Standards.

As the First Circuit recognized and Respondent further explains, FDA was never intended to be the sole arbiter of drug safety, and particular not the arbiter of the maximum level of safety that can be expected from prescription drugs. *See* Pet. App. 9a; Resp. Br. 43-45. Respondent correctly observes that the FDCA, as amended, creates a federal bar on the marketing of drugs and then provides a mechanism, via FDA approval, for escaping that federal bar. *Id.* But the lifting of the federal prior restraint on marketing a drug is not the same as granting manufacturers blanket and preemptive authorization or immunity from other constraints that may operate at the state level.[4]

Petitioner thus is flatly wrong in its repeated mischaracterization of the FDCA and FDA as having conferred upon it "the right to engage in interstate commerce free from state-law liability" Pet Br. at 40;

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[4] For example, there is no federal law *forbidding* individuals from driving at 100 mph, but there is likewise no federal right to do so. The absence of a federal prohibition does not imply a federal right. States may forbid that which federal law merely permits, but does not compel or grant a right to do.

see also id. (quoting case discussing " 'the exercise of * * * federally protected rights.' ") (citation omitted).[5]

One further point of note regarding the role of FDA is that when a court or jury applying state law imposes liability for the sale of a drug permitted on the market by FDA, it is not "second guess[ing]" FDA. Pet. Br. 56. Rather, it is answering an entirely different question. FDA is and remains the exclusive authority on whether a drug has satisfied the minimum *federal* standards necessary to remove the federal bar to marketing. If FDA determines that a drug has not met those standards, marketing remains prohibited, and no State or jury applying state law could change that result and lift the federal ban. But FDA has no authority to opine on anything beyond whether federal minimum standards are met, is never asked whether a drug meets a higher or different standard, and thus has not even offered a *first* guess on the state-law question put to the jury in this case. That is the very nature of deciding minimum rather than maximum safety – while States or juries applying state law cannot decide that *less* safety is appro-

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[5] Petitioner's suggestion, at 58, that the FDCA's procedural protections surrounding the *withdrawal* of FDA approval of a drug application demonstrates a supervening right to market drugs once initially approved is likewise wrong. These procedural protections expressly operate against, and only against, a federal entity and are notably silent regarding any state restrictions on, or liability for, drug sales. Statutory limits on the authority delegated to a federal agent are not even remotely sufficient to grant manufacturers a free-standing right as against the sovereign authority of the States.

priate, they are free to decide that minimum federal safety is insufficient. FDA thus cannot be "second" guessed on a question that it has not answered and lacks the authority to answer.

B. The Hatch-Waxman Act Only Provides an Alternative Path for Meeting Federal Minimum Safety Requirements, Not Blanket Immunity from State Law.

In addition to misconceiving the purposes and operation of the FDCA and the role and authority of FDA, Petitioner also misconceives the purposes and operation of the Hatch-Waxman Act and even the relevance of that Act to this case. While this case happens to involve a manufacturer of a generic drug, it has *nothing* to do with any differences between generic and branded manufacturers. For purposes of strict liability, both types of manufacturers face identical risks and have identical options on how to respond to such risks. Any suggestion that the Hatch-Waxman Act provides generic manufacturers with unique immunity relative to their branded counterparts is absurd.

As explained by Respondent, at 54-55, compliance with the Act merely puts generic manufacturers in the same position as branded manufacturers – approval of an application to market a generic version of a drug is not blanket authority or a federal "right" to market that drug, but rather just the removal of the pre-existing federal impediment to such marketing.

The purpose of Hatch-Waxman was to eliminate unnecessary obstacles to competition and put generic

manufacturers on comparable footing with brand manufacturers, who had the opportunity to amortize their up-front NDA expenses over the life of their patent monopoly. But the notion that Hatch-Waxman gives generics a *greater* right to sell drugs free from state-law liability than their branded counterparts is nowhere to be found in the Act or elsewhere.[6]

The nature of New Hampshire's strict liability cause of action illustrates why there is nothing in the Hatch-Waxman Act that would distinguish generic manufacturers in this area.

Strict liability in New Hampshire makes a company financially responsible for the injuries resulting from products that are unreasonably dangerous notwithstanding the presence of a warning. As the district court recognized, under New Hampshire law, "the plaintiff must prove that the product was unreasonably dangerous *despite* any warning in place at the time of its sale." [JA343 (emphasis in original)] Indeed, it is irrelevant to the tort whether the warn-

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[6] The supposed "sameness" requirement on which Petitioner rests so much actually has nothing to do with this case and does not impose any unique constraints on generic manufacturers. Faced with an unreasonably dangerous drug, branded manufacturers are no more capable of changing the composition of the drug than are generic manufacturers. In either case a change would create a new drug and require a new NDA. The issue here thus has nothing to do with any unique restrictions on generics, as in failure-to-warn cases, but on a straight-forward reading of the FDCA and the fact that it grants no federal *right* to market an unreasonably dangerous drug – whether branded or generic – free from state-law liability.

ing is legally or factually adequate to apprise doctors or patients of the danger, and a "jury could conclude that a product is unreasonably dangerous even if its warning is adequate, or better than adequate." [JA344 (citations omitted)]

The removal of Bextra from the market perfectly illustrates why this case is not about the adequacy of the warnings and does not implicate any difference in generic manufacturers' ability to change their warnings. Bextra had the strongest warning available – a black-box warning – yet FDA still deemed its dangers to outweigh its limited to non-existent benefits in light of the many other NSAIDs on the market. The precise same reasoning is true with sulindac as well – higher risk than other drugs in its class, and no comparative advantage to such drugs, makes it unreasonably dangerous.

By permitting liability for the injuries caused by certain unreasonably dangerous drugs notwithstanding the adequacy of the warning and notwithstanding any notions of "fault" – *i.e.*, *strict* liability – this area of the common law is quite different than most other torts. Rather than being designed to deter and compensate for blameworthy conduct, it merely seeks to internalize and hence spread the cost of unavoidably dangerous products. Much like worker compensation programs, it essentially constitutes a limited insurance program recognizing that while there will be inevitable adverse consequences from certain activities, the costs of those consequences for drugs with an unfavorable cost-benefit ratio should be built into the price and borne by all, rather than borne primarily by

the few individuals unfortunate enough to suffer the consequences directly.[7]

Petitioner and its *amici* make much of the notion that by imposing such financial responsibility on generic drug-makers, strict liability might drive them out of the business of selling certain drugs or at least raise the prices they must charge for such drugs. But to the extent that being required to internalize the costs of injuries would make a drug more expensive and potentially unprofitable, that economic truism applies equally to branded and generic manufacturers, reflects the efficient operation of the market, and certainly does not conflict with anything in the Hatch-Waxman Act.

As long as a product continues to be in demand and profitable at its true (fully-cost-internalized) price, manufacturers – both generic and branded – have every incentive to sell it at the lowest competitive price possible. However, if the fully internalized cost of a product is such that there is no demand for, or profit from, such product, then it is indeed likely that *all* manufacturers would cease to sell such a product. But that is a consequence of the market and

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[7] Strict liability is not really a design defect claim, it is an inherent danger claim where the danger is unreasonable. Petitioner's claim that the design of a generic drug must be "the same" as the branded drug thus is a red herring. A finding of unreasonable danger would apply equally to the branded and generic versions of a drug, assuming they were in fact the same. Neither manufacturer has any relative advantage in how to respond to the conclusion that the drug they are selling is unreasonably dangerous.

competition from numerous other drugs with a better cost-benefit ratio and hence a lower internalized cost.

Because branded and generic manufacturers face the same cost structure and choices under strict liability, they will continue to face competition on equal footing and thus drive the price down as close to marginal cost as is economically feasible. And if the answer is the drug is not economically viable in light of its costs and dangers, then nothing in federal law insists that such a drug remain on the market absent unique circumstances not applicable here.

Finally, Petitioner argues that the "stop-selling-or-pay" theory of the court of appeals below would have led to a different result in *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567 (2011), and hence is untenable. Apart from the fact that generic and branded manufacturers were not on equal footing in connection with their ability to change their warnings, there is nothing wrong with the notion that a different legal argument could have led to a different result in *Mensing*. Many cases decide narrow issues as they are presented to the Court, with the clear possibility that some other, un-argued, issue, might have led to a different outcome. Whether by waiver, failure to include an argument in the Questions Presented, or otherwise, earlier cases often reach a result that would not survive later cases deciding different, yet supervening, issues. *Compare, e.g., United States* v. *United Foods, Inc.*, 533 U.S.405, 416-17 (2001) (holding that compelled support of commodity advertising violated the First Amendment and declining to address government speech argument because not timely raised by the government), *with Johanns* v. *Livestock Market-*

ing Ass'n, 544 U.S. 550, 562-65 (2005) (holding that compelled support of commodity advertising involved government speech not subject to First Amendment compelled-subsidy challenge). Although there are ample grounds for distinguishing the causes of action here and in *Mensing*, even if there were not, that is entirely untroubling given the supervening answer given by the First Circuit in this case, but not presented to, or decided by, this Court in Mensing.

CONCLUSION

For the reasons above, this Court should affirm the decision below.

Respectfully submitted,

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MUTUAL PHARMACEUTICAL COMPANY, INC.,

Petitioner,

v.

KAREN L. BARTLETT,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The First Circuit

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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

Amici are professors who regularly teach and write about the law of torts. Each has taught for 20 years or more and each has written extensively in the field. *Amici* have no stake in the outcome of this case other than their academic interest in the logical and rational development of the law. Because this case implicates fundamental tort law issues, *amici* believe that their unique perspective may assist the Court in resolving this case. The Appendix includes further biographical information.

SUMMARY OF ARGUMENT

Petitioner misconstrues the role of strict product liability for design defects in the regulatory scheme. Such liability does not impose any affirmative duties on manufacturers with respect to the design and distribution of their products. Rather, strict liability allocates responsibility for accident costs to manufacturers to serve several important non-fault-based goals. Strict liability in this context ensures that victims are not denied compensation due to evidentiary and privity hurdles, allocates accident costs to

[1] The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part and no person other than *amici* and their counsel made a monetary contribution intended to fund its preparation or submission.

the party best able to bear and distribute them, and encourages manufacturers to consider whether and in what quantity to produce and distribute their products on the market.

With respect to the manufacture of prescription drugs, those important social goals often give way to the more compelling need in society for innovation and distribution of pharmaceuticals. When prescription drugs provide important social benefits yet remain unavoidably unsafe, comment k to Restatement (Second) of Torts § 402A (1965) exempts their manufacturer from strict liability. That exemption from the background assumption of strict products liability is available to defendants as an affirmative defense, by pleading and proving the basic elements of comment k itself, or by satisfying the state's risk-utility analysis. In either case, the burden is on the defendant to prove the elements of the affirmative defense, and petitioner – having waived its comment k defense before trial – cannot seek the benefit of it in this Court.

The Solicitor General has misconstrued the New Hampshire law of products liability for design defect. The New Hampshire strict liability doctrine applies without regard to fault or the breach of a legal duty to allocate to defendants the costs of injuries caused by the manufacture of unreasonably dangerous products. That doctrine differs from a no-fault liability regime in that it applies only in the narrow category of cases in which the product is found to be unreasonably

unsafe. Nonetheless, it is employed expressly for the purpose of spreading the risk of such injuries.

Nor does the New Hampshire strict liability regime include a "duty to warn" that implicates this Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). In New Hampshire, the presence or absence of a warning may be, but is not necessarily, a factor in determining if a product is unreasonably dangerous. In a case such as this, in which a warning would have been futile, the presence or absence of a warning would be irrelevant to the resolution of a design defect claim.

ARGUMENT

I. Strict Liability For Design Defects Does Not Impose Affirmative Duties On Manufacturers, But Rather Allocates Responsibility For Accident Costs To Manufacturers To Serve Important Non-Fault-Based Goals

States have adopted strict products liability for defective designs in order to advance social goals that are not premised on any fault-based behavior of the manufacturer. As a result, liability for design defects does not impose affirmative duties on manufacturers except to assume a "special responsibility toward any member of the consuming public who may be injured by" the product. Restatement (Second) of Torts § 402A, comment c (1965).

A. Unlike traditional tort liability, strict liability for design defects is a special rule that applies without regard to whether a manufacturer has breached any affirmative duty

Traditional tort liability is fault-based. Negligence liability, for example, is premised on a breach of the affirmative duty to use reasonable care. *See* Gregory C. Keating, *Nuisance as a Strict Liability Wrong*, 4 J. TORT LAW 1, 3 (2012) ("When liability is predicated on fault, the law targets the conduct responsible for the infliction of injury. A judgment of fault asserts that defendant's conduct was wrongful, that the defendant should have conducted itself differently and thereby avoided inflicting injury."); *see also* John C.P. Goldberg & Benjamin C. Zipursky, *Tort Law and Moral Luck*, 92 CORNELL L. REV. 1123, 1167 (2007) ("[T]ort law fashions a set of obligations that help maintain civil society as a non-atomistic, not purely contractual social world."). Similarly, failure-to-warn claims are negligence claims premised on a duty to provide an adequate warning. *See, e.g.*, MICHAEL I. KRAUSS, PRINCIPLES OF PRODUCTS LIABILITY 104-108 (2011); *see also* John L. Watts, *Fairness and Utility in Products Liability: Balancing Individual Rights and Social Welfare*, 38 FLA. ST. U. L. REV. 597, 632 (2011) (noting that the modern approach to duty-to-warn cases, "despite the strict liability misnomer used by some courts, is identical to a negligence approach"). Because the substance of a state-law failure-to-warn claim is the assertion that

the manufacturer has acted unreasonably in failing to provide an adequate warning, successful failure-to-warn claims reflect a state-imposed affirmative duty to provide a particular type of warning. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2573 (2011) ("It is undisputed that Minnesota and Louisiana tort law require a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe.").

Strict liability for design defects, by contrast, is a limited but important exception to this basic fault-based regime. Unlike negligence liability, strict liability is not premised on the blameworthiness of the tortfeasor. Kenneth S. Abraham, *Strict Liability in Negligence*, 61 DEPAUL L. REV. 271, 274 (2012) ("It would be difficult to exaggerate the extent to which the distinction between negligence and strict liability is embedded in tort law. . . . Negligence is the failure to exercise reasonable care; strict liability is the imposition of liability even when reasonable care has been exercised."). "Whereas negligence addresses responsibility for harm which should have been avoided, strict liability addresses responsibility for harm which should *not* have been avoided, and focuses on who should bear the costs of that harm." Keating, *supra*, 4 J. TORT LAW at 6; *see also Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 833 (Neb. 2000) ("In a cause of action based on negligence, the question involves the manufacturer's conduct, that is, whether the manufacturer's conduct was reasonable in view of the foreseeable risk of injury; whereas in a

cause of action based on strict liability in tort, the question involves the quality of the product, that is, whether the product was unreasonably dangerous."); JOHN C.P. GOLDBERG & BENJAMIN C. ZIPURSKY, TORTS 90 (2010) (explaining the distinction, of "theoretical and practical significance," between "negligence law's ordinary care standard and the idea of strict liability, also known as no-fault liability"). Strict products liability for design defect is a classic example of no-fault strict liability. As section 402A of the Restatement (Second) of Torts makes clear, strict liability for design defects is a "special rule . . . making the seller subject to liability to the user or consumer even though he has exercised all possible care in the preparation and sale of the product." Restatement (Second) of Torts § 402A, comment a (1965).

The controversy surrounding Restatement (Third) of Torts: Products Liability § 2(b) (1997) – and its subsequent rejection by many states, including New Hampshire – further evidences the importance to the strict-liability inquiry under the Restatement (Second) of considerations beyond the tort concepts of fault and duty. Section 2(b) seeks to recharacterize design-defect liability as a fault-based standard applying traditional negligence balancing factors, including the requirement that the plaintiff present evidence of a safer alternative design. The Restatement (Third) has been the subject of substantial scholarly criticism. *See, e.g.*, John F. Vargo, *The Emperor's New Clothes: The American Law Institute Adorns a "New Cloth" for Section 402A Products*

Liability Design Defects – A Survey of the States Reveals a Different Weave, 26 U. MEMPHIS L. REV. 493 (1996); David A. Logan, *When the Restatement is not a Restatement: The Curious Case of the "Flagrant Trespasser,"* 37 WM. MITCHELL L. REV. 1448, 1462 (2011) ("Born in controversy and at odds with the original rationales for and concepts of strict liability, the core provisions of the products liability project were perceived as anti-consumer. And, as critics predicted, in the ensuing years, key new provisions have been rejected by some courts because the rules go 'beyond the law,' set the bar for recovery too high, and amount to a 'regression in the law.'") (footnotes and citations omitted). In addition, several states, including New Hampshire, have rejected § 2(b) precisely because it is insufficiently attentive to the non-fault-based goals served by strict liability for design defects. *See, e.g., Vautour v. Body Masters Sports Industries, Inc.*, 784 A.2d 1178, 1182-84 (N.H. 2001) (explaining that § 2(b) undermines the goal of consumer compensation); *Halliday v. Sturm, Ruger & Co.*, 792 A.2d 1145, 1154 (Md. 2002) (noting that "[s]ubstitution of a risk-utility analysis . . . , especially as formulated in the RESTATEMENT (THIRD), has attracted considerable criticism and has been viewed by many as a retrogression, as returning to negligence concepts and placing a very difficult burden on plaintiffs").

B. Strict liability for design defects serves three important non-fault-based goals

Not being fault-based, the strict liability design-defect regime imposes no affirmative duties on manufacturers. Rather, a strict liability regime allocates accident costs to manufacturers, without regard to the breach of any duty, in order to serve several non-fault-based social goals. *See* William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099, 1122-24 (1960) (explaining that strict liability has been adopted by courts to serve three non-fault-based goals); *see also* Mary J. Davis, *Design Defect Liability: In Search of a Standard of Responsibility*, 39 WAYNE L. REV. 1217, 1226-27 (1993) (discussing the goals of strict liability for design defects).

1. Strict liability for design defects ensures that consumers are compensated for their injuries

Strict liability eliminates privity requirements and evidentiary barriers, thereby ensuring that consumers injured by unreasonably dangerous products are compensated for their injuries. Prosser, 69 YALE L.J. at 1123-24 (Obtaining compensation for injuries caused by defective products in the absence of strict liability "is an expensive, time-consuming, and wasteful process, and it may be interrupted by insolvency, lack of jurisdiction, disclaimers, or the statute of limitations, anywhere along the line. What is needed is a blanket rule which makes any supplier in

the chain liable directly to the ultimate user, and so short-circuits the whole unwieldy process."); *see also Brooks v. Beech Aircraft Corp.*, 902 P.2d 54, 58 (N.M. 1995) ("[P]laintiffs injured by an *unreasonably* dangerous product should be compensated for their injuries. At the heart of this judgment lies the conclusion that although the manufacturer has provided a valuable service by supplying the public with a product that it wants or needs, it is more fair that the cost of an *unreasonable* risk of harm lie with the product and its possibly innocent manufacturer than it is to visit the entire loss upon the often unsuspecting consumer. . . .").

2. Strict liability for design defects imposes costs on the party that is best able to either bear or redistribute them

Imposing accident costs on manufacturers without regard to fault allocates risks and costs to the party best able to bear or redistribute them. Prosser, 69 YALE L.J. at 1122 (explaining that strict liability "justifies the imposition, upon all suppliers of such products, of full responsibility for the harm they cause, even though the supplier has not been negligent"); *see also Azzarello v. Black Brothers Co.*, 391 A.2d 1020, 1023 (Pa. 1978) ("The realities of our economic society as it exists today forces the conclusion that the risk of loss for injury resulting from defective products should be borne by the suppliers, principally because they are in a position to absorb

the loss by distributing it as a cost of doing business.").

3. Strict liability for design defects ensures that manufacturers bear the full costs their products impose on society, thereby encouraging them to reduce that risk by controlling their activity level

By imposing the costs of accidents on manufacturers without regard to fault, a strict liability regime ensures that manufacturers bear the full costs that their products impose on society. Only if all the costs are included in a manufacturer's production decisions can it accurately determine how much of the unreasonably dangerous product to sell, or even whether to sell it at all. As Professor Kenneth Abraham recently explained:

> Exercising reasonable care does not eliminate the risk of injury. Other things being equal, therefore, the more a party engages in an activity, even if she exercises reasonable care, the more often injury or damage will result. The threat of liability for negligence thus generates no incentive to determine whether it would be more sensible to engage in less of the activity because exercising reasonable care will insulate a party from any liability for injury or damage that results from engaging in the activity. . . .

> Threatening to impose strict liability for injury or damage resulting from engaging in an activity can therefore create an additional incentive. Because a party will be held liable even for harm that results when it exercises reasonable care, liability costs can be reduced by engaging in less of the activity or partially or fully substituting a different, cost-effective activity.

Abraham, *supra*, 61 DEPAUL L. REV. at 278-279; *see also Indiana Harbor Belt Railroad Co. v. American Cyanamid Co.*, 916 F.2d 1174, 1177 (7th Cir. 1990) (Posner, J.) ("The baseline common law regime of tort liability is negligence. When it is a workable regime, because the hazards of an activity can be avoided by being careful . . . there is no need to switch to strict liability. Sometimes, however, a particular type of accident cannot be prevented by taking care but can be avoided . . . by reducing the scale of the activity in order to minimize the number of accidents caused by it. . . . By making the actor strictly liable . . . we give him an incentive, missing in a negligence regime, to experiment with methods of preventing accidents that involve not greater exertions of care, assumed to be futile, but instead . . . reducing (perhaps to the vanishing point) the activity giving rise to the accident.") (citations omitted); Steven Shavell, *Strict Liability Versus Negligence*, 9 J. LEGAL STUD. 1, 2-3 (1980) (explaining that strict liability can affect activity levels whereas negligence liability tends to affect only safety levels).

This additional goal of strict liability – to encourage manufacturers to consider and, in certain cases, adjust their activity level with respect to unreasonably dangerous products if, despite taking all reasonable care in the manufacturing of the product, the product's risks still outweigh its utility – comports with the First Circuit's recognition that federal law does not require drug manufacturers to sell their products. Pet. App. 10a ("But although [petitioner] cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway), it certainly can choose not to make the drug at all. . . .").

C. None of the important non-fault-based goals served by the application of strict liability for design defects imposes affirmative duties on manufacturers beyond the duty to assume the costs of injuries resulting from their products

None of these social goals is premised on fault-based duties, and none imposes any affirmative requirements on manufacturers. Under a strict liability design-defect regime, the manufacturer of an unreasonably dangerous product is faced with only one obligation as a result of marketing its product – the obligation to assume the costs of any injuries that might occur as a result of its actions. This obligation does not entail a judgment that the action was blameworthy, or, concomitantly, that the action

should be avoided. *See* Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055, 1060-61 (1972) ("Instead of requiring a judgment as to whether an injurer *should* have avoided the accident costs because the costs of avoidance were less than the foreseeable accident costs as the [negligence] test does, the strict liability test would simply require a decision as to whether the injurer or the victim was in the better position both to judge whether avoidance costs would exceed foreseeable accident costs and to act on that judgment. The issue becomes not *whether* avoidance is worth it, but which of the parties is relatively more likely to find out whether avoidance is worth it.") (footnote omitted).

In asserting (at 41) that "all common law liability is premised on the existence of a legal duty" (citations and quotations omitted), petitioner ignores these important distinctions between negligence and strict liability.

Petitioner also conflates state tort liability in the context of federal regulatory schemes that expressly preempt additional state-law requirements or occupy the field with the effect of tort liability in areas in which Congress has evidenced no intent to preempt all state-law claims. In an area in which Congress has expressly preempted state requirements "different from, or *in addition to*," federal requirements, Congress has determined that federal law sets a ceiling on the regulatory requirements to which a manufacturer should be subject. *Riegel v. Medtronic,*

Inc., 552 U.S. 312, 321 (2008) (emphasis added; internal quotation marks omitted). Similarly, in regulatory schemes that occupy the field in which they operate, federal decisions not to regulate are as important as decisions to take affirmative action. *See, e.g., San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 248 (1959) ("Even the States' salutary effort to redress private wrongs or grant compensation for past harm cannot be exerted to regulate activities that are potentially subject to the exclusive federal regulatory scheme [embodied in the NLRA]."). Thus, the imposition of damages pursuant to a state-law action may alter behavior in a field that Congress has chosen to occupy, impermissibly interfering with federal decision-making in a pervasively regulated field. *See Kurns v. Railroad Friction Products Corp.*, 132 S. Ct. 1261, 1269-70 (2012); Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 261-262 (2000) (discussing the effect of state liability in the context of field preemption and noting that in cases of field preemption, "if a state purports to regulate the forbidden field, a court would have to choose between giving legal effect to the state regulation and giving legal effect to the federal rule depriving such regulations of authority").

In an area governed by conflict preemption, however, only those state-law obligations that affirmatively conflict with a federal requirement are preempted. The imposition of strict liability for design defects does not assign fault and does not demand any affirmative action, except to assume the cost of

injuries caused by unreasonably dangerous drugs. Unlike the duty to provide an adequate warning, which in the case of generic drugs is impossible to discharge under current FDA regulations, *see PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the duty to compensate consumers injured by unreasonably dangerous drugs has no FDA counterpart with which it could conflict. Thus, compliance with both federal regulations and state law is not a "physical impossibility." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963).

Nor does the incentive created by strict design-defect liability for manufacturers to consider how much of the drug (if any) to market in a particular state conflict with any affirmative duty imposed by the FDCA. Approval by the FDA is a prerequisite for introducing drugs into the market. 21 U.S.C. § 355(a). The FDCA does not, however, "expressly require that an approved drug be made available in any particular State or that the manufacturer be guaranteed the ability to make it so." U.S. Br. 21. In the context of state law design-defect claims, there is neither a federal affirmative duty to market a drug, nor a state affirmative duty to cease marketing the drug, and thus no conflict exists. The FDA's role in prescription drug regulation leaves important room in the regulatory scheme for states to create incentives for manufacturers to remove drugs from the market if the incremental risk of offering the drug to consumers outweighs its incremental benefits, even if that drug is approved for marketing by the FDA.

Contrary to the Solicitor General's assertion (at 18-20), the *Mensing* Court did not reject the complementary nature of the incentive to decrease or cease marketing operations of an unreasonably dangerous but FDA-approved drug. As the Solicitor General concedes, respondents in *Mensing* did not raise that argument and therefore this Court did not address it. *See* U.S. Br. at 19 n.4; *see also Mensing*, 131 S. Ct. at 2587 n.8 (Sotomayor, J., dissenting) (noting that the decision below had "suggested" that the manufacturers could not show impossibility because federal law merely permitted them to market generic drugs but did not require them to do so, and stating that "Respondents have not advanced this argument, and I find it unnecessary to consider.").[2]

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[2] The *Mensing* plaintiffs belatedly advanced the argument in a rehearing petition, which this Court summarily denied. *See PLIVA, Inc. v. Mensing*, 132 S. Ct. 55 (2011). That summary denial lacks precedential force and does not control here. *See Connecticut v. Doehr*, 501 U.S. 1, 12 n.4 (1991) ("A summary disposition does not enjoy the full precedential value of a case argued on the merits and disposed of by a written opinion."); *Fernandez v. Chardon*, 681 F.2d 42, 51 n.7 (1st Cir. 1982) ("denial of a petition for rehearing can have no greater precedential effect than the denial of a petition for certiorari, which is to say none").

II. Most States Follow The Restatement In Providing An Exemption From Strict Liability For Design Defects In Prescription Drugs If The Manufacturer Proves That The Drug Is Unavoidably Unsafe, But Petitioner Has Waived This Affirmative Defense

As discussed above, strict products liability for design defects is a limited exception to the general fault-based negligence regime. Within this small window of strict liability, the Restatement (Second) recognizes that some products are incapable of being made safe for their intended use but are nonetheless so socially important that the compensation, risk-spreading, and activity-level incentives of strict liability are inappropriate. Restatement (Second) § 402A, comment k. Comment k labels such products "unavoidably unsafe" and exempts the manufacturer of those products from strict liability for design defects. Some states apply the exemption on a case-by-case basis, even to prescription drugs, while others have held that all prescription drugs are exempted from strict liability for design defects. Whether applied as blanket immunity or in individual cases, the exemption from strict liability for prescription drugs under comment k has been generously available to manufacturers of prescription drugs. In all events, however, the exemption offered by comment k is an affirmative defense to strict liability, and that defense must be pleaded and proved by the manufacturer.

A. Consistent with the importance of the goals underlying strict liability for design defects, comment k is best read not to confer blanket immunity from strict liability on all prescription drugs

Comment k exempts from strict liability those products "which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts § 402, comment k. While pharmaceuticals may fall into this category, there is no reason to believe that *all* drugs will satisfy the comment k criteria. Indeed, the comment itself makes clear that there will be drugs that do not satisfy the criteria by noting that such unavoidably unsafe products "are *especially common* in the field of drugs." *Id.* (emphasis added). The comment further identifies the Pasteur treatment for rabies as an example of a product deserving immunity, and then notes that "the same is true of many other drugs, vaccines, and the like." If comment k were intended to indicate that blanket immunity for all prescription drugs was appropriate, it would make no sense to offer examples of drugs that may qualify for such immunity. Thus, while it may be especially common for pharmaceuticals to qualify as unavoidably unsafe products, comment k should not be read to provide a blanket exception from strict liability for *all* drugs.

Given the importance of the policies underlying strict scrutiny for defective products, many states

apply comment k to prescription drugs only if the manufacturer can demonstrate that the drug is unavoidably unsafe. *See Freeman*, 618 N.W.2d at 836 (noting that "[t]he majority of jurisdictions that have adopted comment k. apply it on a case-by-case basis, believing that societal interests in ensuring the marketing and development of prescription drugs will be adequately served without the need to resort to a rule of blanket immunity") (overruling prior decision to the contrary); *see also Feldman v. Lederle Laboratories*, 479 A.2d 374, 383 (N.J. 1984) ("Whether a drug is unavoidably unsafe should be decided on a case-by-case basis; we perceive no justification for giving all prescription drug manufacturers a blanket immunity from strict liability . . . design defect claims under comment k."); *Hill v. Searle Laboratories*, 884 F.2d 1064, 1069 (8th Cir. 1989) ("The better reasoned opinions support the view that the unavoidably unsafe exception should only apply [to prescription drugs] upon a showing of exceptional social need."); *cf. Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 (Okla. 1994) (holding that comment k *can*, not *must*, apply to medical devices).

Although New Hampshire courts have not spoken definitively to the issue, there is no reason to believe that they would interpret comment k as an across-the-board exemption from strict liability for all prescription drugs. *See Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 655 (1st Cir. 1981) ("We are unwilling to say that under New Hampshire's balancing test no drug can ever be classified as

unreasonably dangerous."). The New Hampshire Supreme Court's refusal to adopt the stricter § 2(b) of the Restatement (Third) over its more relaxed Restatement (Second) counterpart, *see Vautour*, 784 A.2d at 157, because it would "impose an undue burden on plaintiffs" further suggests that it would reject a blanket immunity for prescription drug manufacturers under comment k. *Cf. Freeman*, 618 N.W.2d at 840 (rejecting Restatement (Third) § 6(c), which provides more extensive immunity for prescription drug manufacturers, because it "has no basis in the case law" and is "too strict of a rule, under which recovery would be nearly impossible."). States adopting the case-by-case approach have, in essence, concluded that "[i]t does not serve society that an unavoidably unsafe product, which has occasional or fractious benefit, should enjoy insulation from strict liability in tort when the product's predominant effects are detrimental to individual and public safety." Sidney H. Willig, *The Comment* k *Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545, 545 (1978).

In states adopting the case-by-case application of comment k, determining whether a product – even a pharmaceutical product – is unavoidably unsafe requires a weighing of relevant risk-utility factors. *See Freeman*, 618 N.W.2d at 837 ("Although a variety of tests are employed among jurisdictions that apply comment k. on a case-by-case basis, the majority apply the comment as an affirmative defense, with the trend toward the use of a risk-utility test to determine whether the defense applies."); *see also*

Tansy, 890 P.2d at 886 (embracing the holdings of other courts that "a risk-utility analysis must be employed before Comment k will bar recovery under products liability"). Relevant factors include: "(1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product was both 'substantial' and 'unavoidable'; and (3) whether the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review." *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 925 (Kan. 1990) (quoting and expressly adopting the reasoning of *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812 (1985), *overruled by Brown v. Superior Court (Abbot Labs)*, 751 P.2d 470 (1988)); *see also Toner v. Lederle Laboratories*, 732 P.2d 297, 306 (Idaho 1987). This risk-utility analysis complements, rather than conflicts with, the FDA's drug approval process. *See Feldman*, 479 A.2d at 383 ("Indeed, the FDA's determination, even if it consisted of a risk-utility analysis, would not supplant the risk-utility balancing required in the judicial process.").

To be sure, some states have taken a more expansive view of the exemption offered in comment k. Those states generally hold that a prescription drug that is properly manufactured and accompanied by an adequate warning of the risks known to the manufacturer at the time of the sale is not defectively designed as a matter of law. *See, e.g., Young v. Key*

Pharmaceuticals, Inc., 922 P.2d 59, 64 (Wash. 1996) (en banc); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 90 (Utah 1991); *Brown*, 751 P.2d at 478-480. Those states have concluded that the non-fault-based goals of strict liability in design defect are superseded by the recognition of the unique nature and value of prescription drugs, *Grundberg*, 813 P.2d at 95, and concerns that the added expense of providing compensation for injuries caused by prescription drugs will discourage or delay innovation in the pharmaceutical industry. *See, e.g., Brown*, 751 P.2d at 479-480.

B. Exemption from liability under comment k is an affirmative defense, and the burden is on the manufacturer to raise and prove the elements of this defense

Regardless whether it is applied on a case-by-case basis or across the board, whether comment k insulates a drug manufacturer from strict liability for design defects is an affirmative defense. *See Tansy*, 890 P.2d at 886 ("The Comment does not provide blanket protection for all medical devices. Rather, it applies only as an affirmative defense. . . ."). An affirmative defense is "[a] defendant's assertion of facts and arguments that, if true, will defeat the plaintiff's . . . claim, even if all the allegations in the complaint are true." BLACK'S LAW DICTIONARY 451 (8th ed. 2004).

Because it is an affirmative defense, the defendant bears the burden of proving all of the elements of the defense. *See Tansy*, 890 P.2d at 886; *Coursen v. A.H. Robbins Co.*, 764 F.2d 1329, 1338 (9th Cir. 1985); *see also* Pet. App. 127a ("courts generally place the initial burden of proving the various [comment k] factors on the defendant"; holding plaintiff's design defect claim survived summary judgment) (internal quotation marks omitted). Thus, once the plaintiff's prima facie case for design defect is established, a manufacturer will be relieved of strict liability only when it demonstrates that its product satisfies the relevant state law criteria for establishing that its product is unavoidably unsafe. *See Freeman*, 618 N.W.2d at 840.

Petitioner (at 34-35) and the Solicitor General (at 17) claim that a defective-drug-design claim often overlaps with a failure-to-warn claim via the comment k affirmative defense. They argue that defective-drug-design claims are therefore preempted under this Court's reasoning in *Mensing*. That argument is both speculative and irrelevant. First, the New Hampshire Supreme Court has not yet embraced comment k and thus has not specified the elements of that defense if applicable in New Hampshire. Second, as noted above (at 19-20), relevant precedent suggests that New Hampshire would adopt a case-by-case risk-utility version of the comment k defense, which does not necessarily include an inquiry into the adequacy of the manufacturer's warning. Finally, and most importantly, petitioner lost any

opportunity it might have had to implicate the adequacy of its warning in Respondent's design defect claim when it waived its comment k defense "on the eve of trial." *See* Pet. App. 36a, 60a-61a.

III. Under New Hampshire Law, Strict Liability In Tort Is Consistent With The General Non-Fault-Based Goals Of Ensuring Compensation, Allocating Costs To The Party Best Able Either To Bear Or To Redistribute Them, And Ensuring That Manufacturers Internalize External Costs

The general principles discussed above are applicable in New Hampshire. The New Hampshire Supreme Court has expressly recognized and adopted the goals of strict liability that have been followed elsewhere.

A. The New Hampshire Supreme Court adopted the principles of Restatement § 402A to ensure that the risks of unreasonably dangerous products would "be borne by the companies that profited from their sale, rather than by the unfortunate individual consumers"

Prior to 1969, New Hampshire followed the traditional common-law rule under which a plaintiff generally could not recover for injuries caused by a defective product unless he or she could prove a breach of warranty or negligence on the part of the defendant. *See, e.g., Smith v. Salem Coca-Cola*

Bottling Co., 25 A.2d 125 (N.H. 1942); *Howson v. Foster Beef Co.*, 177 A. 656 (N.H. 1935). Thus "a products liability claim was actionable under warranty and negligence theories," but not under "the strict liability concept." *Waid v. Ford Motor Co.*, 484 A.2d 1152, 1155 (N.H. 1984); *see also, e.g., Bagley v. Controlled Environment Corp.*, 503 A.2d 823, 825 (N.H. 1986) (Souter, J.) ("strict liability for damages has traditionally met with disfavor in this jurisdiction").

In *Buttrick v. Arthur Lessard & Sons*, 260 A.2d 111 (N.H. 1969), the New Hampshire Supreme Court first held that an injured plaintiff may proceed against the non-negligent seller of a defective product under "the theory of strict liability in tort as defined in Restatement (Second), Torts, [§ 402A]." 260 A.2d at 112. After quoting the full text of § 402A, the court explained:

> The basis for the present rule of strict liability is the "ancient one of the special responsibility for the safety of the public undertaken by one who enters into the business of supplying human being[s] with products which may endanger the safety of their persons and property, and the forced reliance upon that undertaking on the part of those who purchase such goods."

260 A.2d at 113 (quoting Restatement § 402A, comment f).

Subsequent cases have explained in greater detail that the purpose of the strict liability remedy is

to require those who sell unreasonably dangerous products to internalize the cost of the harm caused by those products. In *Heath v. Sears, Roebuck & Co.*, 464 A.2d 288, 293 (N.H. 1983), for example, the court noted that there were "many" "reasons for the evolution of the law in the area of products liability," but it relied primarily on the belief "that if today's products are capable of causing illness or physical injury, the risk of liability is best borne by the companies that profited from their sale, rather than by the unfortunate individual consumers."

B. The New Hampshire strict liability doctrine applies to cases in which a defendant has breached no legal duty

The New Hampshire Supreme Court has frequently noted that its strict liability doctrine applies when a defendant has breached no legal duty. When Justice Souter served on that court, he carefully defined "strict liability" in those terms:

> Legal liability is said to be strict when it is imposed even though the defendant has committed no legal fault consisting of the violation of a common law or statutory duty.

Bagley, 503 A.2d at 825 (Souter, J.). In *Bolduc v. Herbert Schneider Corp.*, 374 A.2d 1187, 1189 (N.H. 1977), the court distinguished strict liability from a common carrier's liability with the observation that "under strict tort liability . . . one may be held liable even though he exercised the highest degree of care

and thus was not negligent." *See also, e.g., Kelton v. Hollis Ranch, LLC*, 927 A.2d 1243, 1246 (N.H. 2007) (quoting *Bagley*).

C. The New Hampshire strict liability doctrine differs from a general "no-fault" liability regime because it applies in only a narrow category of cases

The New Hampshire Supreme Court has made it abundantly clear that the strict liability remedy adopted in *Buttrick* is very different from the no-fault liability for personal injuries that exists in other contexts, such as workers' compensation or no-fault automobile insurance.

Even before *Buttrick*, the New Hampshire Supreme Court emphasized one limit on the strict liability remedy. In *Elliott v. Lachance*, 256 A.2d 153 (N.H. 1969) – a case that was pending at the same time as *Buttrick* but announced five months earlier – the court "presaged" the impending adoption of the Restatement § 402A approach. *Buttrick*, 260 A.2d at 113. Noting three difficulties with bringing a personal injury action under a warranty theory, the *Elliott* court explained that "there has arisen another remedy. . . . It imposes strict liability in tort for the sale of a defective product unreasonably dangerous to an intended user or consumer." 256 A.2d at 155 (citing out-of-state cases, Restatement § 402A, and academic commentary). But the *Elliott* court immediately stressed the limits of the strict liability remedy:

> "Strict liability does not make the manufacturer or seller an insurer nor does it impose absolute liability." . . . In other words, unlike absolute liability, the mere injury from a product does not create liability. . . .
>
> [When] proceeding . . . on a strict tort liability based on a defective product which is unreasonably dangerous, the plaintiff has the burden of proving that her injury resulted . . . from a defect [of the product].

256 A.2d at 156 (quoting *Dippel v. Sciano*, 155 N.W.2d 55, 63 (Wis. 1967)). Because the *Elliott* plaintiff was unable to establish causation, her action failed and it was unnecessary for the court formally to adopt the strict liability approach.

After *Buttrick*, the New Hampshire Supreme Court has limited the scope of the strict liability doctrine in various ways. Perhaps most obviously, the court has repeatedly declined to extend the doctrine outside of the context of defective products. *See, e.g.*, *Bagley v. Controlled Environment Corp.*, 503 A.2d 823 (N.H. 1986) (declining to impose strict liability for environmental damages caused by the discharge of hazardous waste); *Moulton v. Groveton Papers Co.*, 289 A.2d 68, 72 (N.H. 1972) (declining to impose strict liability for flooding damages when a dam failed); *Dumas v. State Farm Mutual Automobile Insurance Co.*, 274 A.2d 781, 784 (N.H. 1971) (declining to impose strict liability for damages caused by an insurer's failure to settle a case within policy limits). As Justice Souter explained in *Bagley*, "this court has

recognized only one cause of action for damages based on strict liability, that being for the benefit of the user or consumer of an unreasonably dangerous and defective product." 503 A.2d at 825 (citing *Buttrick*; Restatement § 402A).

The New Hampshire Supreme Court has also limited the scope of the strict liability doctrine by its narrow reading of the requirements of Restatement § 402A.[3] In particular, the court has construed § 402A(1) – which by its terms covers "any product in a defective condition unreasonably dangerous to the user or consumer" – so that the doctrine applies only when the risks created by the product outweigh the benefits of the product. *See, e.g., Kelleher v. Marvin Lumber & Cedar Co.*, 891 A.2d 477, 492 (N.H. 2005); *Vautour*, 784 A.2d at 1182. "A product's design should meet risk-utility balancing standards as seen from the point of view of the public as a whole." *Price v. BIC Corp.*, 702 A.2d 330, 332 (N.H. 1997); *see also, e.g., Vautour*, 784 A.2d at 1182.

The court has similarly limited the reach of strict liability by its narrow reading of other § 402A requirements. Thus in *Royer v. Catholic Medical Center*, 741 A.2d 74, 76 (N.H. 1999), for example, the

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[3] The court acted quite deliberately in this regard. In *Price v. BIC Corp.*, 702 A.2d 330, 333 (N.H. 1997), for example, it forthrightly "caution[ed] that the term 'unreasonably dangerous' should not be interpreted so broadly as to impose absolute liability on manufacturers or make them insurers of their products."

court "recognized limits to the doctrine" with its restrictive reading of the "seller of goods" requirement.

D. The New Hampshire Supreme Court has recognized that the strict liability doctrine is "a system of spreading the risk"

On a few occasions, the New Hampshire Supreme Court has disclaimed the suggestion "that strict liability is in reality a tool of social engineering, and that manufacturers should be required to bear the entire risk and costs of injuries caused by products." *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 845 (N.H. 1978). *See also, e.g., Heath*, 464 A.2d at 299 (quoting *Thibault*). Those disclaimers, however, simply make the same fundamental point as *Elliott v. Lachance*: strict liability does not guarantee damages for every victim of a personal injury in the same way that a workers' compensation statute provides compensation to those injured on the job or no-fault automobile insurance covers those injured in traffic accidents.

In *Elliott*, strict liability was more limited than under a general no-fault compensation system because the plaintiff could not prove causation. *See* 256 A.2d at 156. *Thibault* similarly stressed that "[t]he plaintiff in a defective design case must . . . prove causation. . ." 395 A.2d at 847; *see also id.* at 850 ("the jury could have found . . . that the [allegedly

defective] design was not the cause of the accident"). Other aspects of the strict liability doctrine limiting its scope, *see supra* at 27-30, likewise distinguish it from a no-fault compensation system. *Thibault* noted some of those limitations, too. *See, e.g.*, 395 A.2d at 846 ("In a strict liability case alleging defective design, the plaintiff must first prove the existence of a 'defective condition unreasonably dangerous to the user.'") (quoting *Buttrick*, 260 A.2d at 113).

In sum, the New Hampshire Supreme Court has not rejected risk-spreading as a justification for the strict liability doctrine. On the contrary, the *Thibault* court itself explicitly noted that "the doctrine of strict liability" could be "[v]iewed as a system of spreading the risk." 395 A.2d at 846. Of course, that internalizing of accident costs "had economic consequences," *id.*, and thus the court would not allow risk-spreading to "undermine[ ] or abolish[ ]" the basic "common-law principle that fault and responsibility are elements of our legal system," *id.* The *Thibault* court accordingly "reaffirm[ed] *Buttrick*" but also "recognize[d] some limits to the doctrine of strict liability." *Id.* In particular, the court confirmed that strict liability is a narrow doctrine subject to specific requirements. *See id.* at 846-850. In the rare cases when the doctrine applies, however, it spreads the risk of loss without regard to the defendant's negligence or other breach of a legal duty by requiring those who sell unreasonably dangerous products to internalize the cost of the harm caused by those products.

IV. New Hampshire's Strict Liability Doctrine In Design-Defect Cases Does Not Include A "Duty To Warn" Element That Implicates *PLIVA, Inc. v. Mensing*.

In *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), this Court held that federal law preempts state tort claims based on a generic drug manufacturer's failure to provide adequate warning that long-term use of its product can cause severe medical problems. The Solicitor General (at 17) argues that *Mensing* controls here because "the state-law duty to design a non-defective product *includes* a duty to provide an adequate warning." The Solicitor General has misunderstood New Hampshire law.

To be sure, "the presence or absence of a warning" is a "factor to be considered" in appropriate cases. *Thibault*, 395 A.2d at 846. *See also, e.g.*, *Vautour*, 784 A.2d at 1182; *Price v. BIC Corp.*, 702 A.2d 330, 333 (N.H. 1997); *Chellman v. Saab-Scania AB*, 637 A.2d 148, 150 (N.H. 1993). But "the presence or absence of a warning" is simply one of many factors to be considered when appropriate. In *Thibault* itself, the court noted that a warning is not necessarily required even when a product is undoubtedly "dangerous." *See* 395 A.2d at 846. Conversely, "when an unreasonable danger could have been eliminated without excessive cost or loss of product efficiency, liability may attach even though . . . there was adequate warning." 395 A.2d at 847.

Here "the presence or absence of a warning" was neither controlling nor dispositive. And the warning's legal "adequacy" was irrelevant. Pet. App. 36a. Examination of the New Hampshire duty-to-warn cases illustrates that a warning is most relevant if the risk of injury is reduced when a consumer uses a potentially dangerous product in a less dangerous manner. In *Chellman*, 637 A.2d at 151, for example, an automobile was unreasonably dangerous in part because the defendants failed to warn of certain handling characteristics. Similarly, in *LeBlanc v. American Honda Motor Co.*, 688 A.2d 556 (N.H. 1997), the defendant had failed to warn of an automobile's braking and steering properties when driven on ice. Significantly, the *LeBlanc* court explicitly declared that "[t]he plaintiff's design defect and failure to warn claims are separate." *Id.* at 562.

In this case, there was no way for a consumer to use sulindac more safely. Respondent did not face a choice between a safe and a dangerous way to administer the drug, as in *Wyeth v. Levine*, 555 U.S. 555, 559 (2009). Respondent would not have escaped her horrific injuries if petitioner had warned her to avoid the long-term use of sulindac; after first taking the drug in December 2004, she "developed SJS/TEN early in 2005." Pet. App. 3a; *cf. Mensing*, 131 S. Ct. at 2572 ("long-term metoclopramide use can cause tardive dyskinesia"). In short, this is a very different case than *Chellman*, *LeBlanc*, *Wyeth*, or *Mensing*. While "the presence or absence of a warning" is a

"factor to be considered" in some cases, it was not dispositive here.

The Solicitor General's argument here is essentially the same as the defendant's argument that the New Hampshire Supreme Court rejected in *Vautour*. The *Vautour* plaintiffs argued that a "leg press machine" was unreasonably dangerous but they offered no evidence of a reasonable alternative design. Prior decisions had held that the availability of a reasonable alternative design – like the presence or absence of a warning – was a "factor to be considered" in appropriate cases. *See*, *e.g.*, *Price*, 702 A.2d at 333; *Thibault*, 395 A.2d at 846. On that basis,[4] the *Vautour* defendant argued that the availability of a reasonable alternative design was part of a defective-design case and that the plaintiffs must offer evidence addressing the issue. Rejecting the defendant's argument, the court explained:

> [W]hile proof of an alternative design is relevant in a design defect case, it should be neither a controlling factor nor an essential element that must be proved in every case. As articulated in *Thibault*, the risk-utility test requires a jury to consider a number of factors when deciding whether a product is unreasonably dangerous. *See Thibault*, [395 A.2d at 846]. This list is not meant to be

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[4] The *Vautour* defendant also relied on Restatement (Third) of Torts § 2(b) (1998), which the New Hampshire Supreme Court "decline[d] to adopt." 784 A.2d at 1184. *See supra* at 20.

> exclusive, but merely illustrative. "Depending on the circumstances of each case, flexibility is necessary to decide which factors" may be relevant. *Armentrout v. FMC Corp.*, 842 P.2d 175, 184 (Colo. 1992) (explaining in dictum that relevant factors cannot be confined to a single list which must always be applied regardless of circumstances). Thus, the rigid prerequisite of a reasonable alternative design places too much emphasis on one of many possible factors that could potentially affect the risk-utility analysis.

784 A.2d at 1183-84. The Solicitor General's argument is no more persuasive here. The presence or absence of a warning is simply "one of many possible factors." It is "neither a controlling factor nor an essential element" of a design-defect case. The Solicitor General "places too much emphasis on one of many possible factors that could potentially affect the risk-utility analysis." Whether any particular factor is relevant "[d]epends on the circumstances of each case." Because no warning could have made respondent's use of sulindac any safer, the factor is simply irrelevant here.

The Solicitor General's argument is also inconsistent with more general tort principles. Many states distinguish design-defect claims from failure-to-warn claims. Restatement (Third) § 1, comment a, reporters' note 1, recognizes "[a]bundant authority" in numerous jurisdictions for differentiating between claims alleging "design defects" and those alleging "defects based on inadequate instructions or warnings." Scholarly

commentary, too, has long "recognize[d] the distinction as necessary to a coherent discussion of the bases of liability" for defective products. *Id.*

This Court itself has recognized as "perfectly clear" the distinction between common-law "claims for defective design" and a requirement "that manufacturers label . . . their products in any particular way." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 444 (2005). The *Bates* Court accordingly held that, although federal law in that context might preempt a failure-to-warn claim, it does not preempt design-defect claims.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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APPENDIX

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Thomas C. Galligan, Jr., is President and a professor at Colby-Sawyer College. From 1986 to 1998, he was a professor at LSU's Paul M. Hebert Law Center. From 1998 to 2006, he was the dean of the University of Tennessee College of Law. He is the author or co-author of many books and articles on torts and his scholarship has been extensively cited by courts and scholars. He has testified before Congress and the Louisiana legislature on issues related to torts and product liability.

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AMICUS CURIAE BRIEF

No. 12-142

IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL CO., INC.,

Petitioner,

v.

KAREN L. BARTLETT,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether federal law preempts state law design-defect claims against the manufacturer of a generic version of a prescription drug whose design has been approved by the federal Food and Drug Administration.

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INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government.

To that end, WLF has frequently appeared as *amicus curiae* in this and other federal courts in cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek simultaneously to regulate the same business activity. *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *United States v. Locke*, 529 U.S. 89 (2000).

The Allied Educational Foundation (AEF) is a non-profit charitable foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared as *amicus curiae* in this Court on a number of occasions.

Amici are particularly concerned that individual freedom and the American economy both suffer when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that

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[1] Pursuant to Supreme Court Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, made a monetary contribution intended to fund the preparation and submission of this brief. All parties have consented to the filing of this brief; letters of consent have been lodged with the clerk.

frustrates the objectives or operation of specific regulatory regimes, such as (in this case) the Food, Drug, and Cosmetic Act (FDCA), and that make it impossible for regulated businesses to operate in compliance with both federal and state laws.

At issue here is whether Congress intended to preempt Respondent's cause of action. *Amici* agree with Petitioner that the "sameness" rationale set forth in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), is dispositive in this case and requires a finding that design-defect claims against generic drug companies such as Petitioner are preempted. *Amici* write separately to focus on an even more fundamental reason why the design-defect claim is preempted. Congress has granted the Food and Drug Administration (FDA) authority to determine whether, based on its safety and effectiveness, a drug should be available for sale in interstate commerce. FDA's statutory authority extends to determining that a previously-approved drug should be removed from the market. Any effort by a State to determine whether an FDA-approved drug should be removed from the market frustrates Congress's statutory scheme. Moreover, state-law mandates of the sort at issue in this case make it impossible for drug companies, whether brand-name or generic, to comply with both federal and state law. Accordingly, basic principles of conflict preemption require dismissal of *all* design-defect claims against the manufacturers of FDA-approved drugs.

Amici have no direct interests, financial or otherwise, in the outcome of this case. They are filing due solely to their interests in the important

preemption issues raised herein.

STATEMENT OF THE CASE

Respondent Karen Bartlett suffered serious and permanently disabling injuries after taking sulindac, an FDA-approved drug manufactured by Petitioner Mutual Pharmaceutical Co., Inc. Sulindac has been widely used to treat arthritis since its initial approval by FDA in 1978. Sulindac was initially marketed by Merck & Co. under the brand name Clinoril®; after Merck's patent expired, Mutual began marketing a generic version in 1991. As required by the FDCA, the sulindac marketed by Mutual has at all times been bioequivalent to, and has borne the same labeling as, Clinoril®.

Bartlett's 2008 suit against Mutual raised a variety of claims under New Hampshire law, including that Mutual inadequately warned Bartlett and/or her physician regarding the dangers of sulindac and that the drug was defectively designed. All claims except the design-defect claim were dismissed from the lawsuit. In particular, the trial judge dismissed the failure-to-warn claim based on lack of causation because Bartlett's doctor did not read the product labeling and thus could not have relied on Mutual's (allegedly inadequate) warning in deciding to prescribe sulindac. Pet. App. 117a-121a.

The only claim presented to the jury was the defective-design claim. The jury awarded Bartlett over $21 million in damages, including $16.5 million in non-economic damages. The trial court denied pre- and post-trial motions asserting that Bartlett's tort claim

was preempted by federal law.

The U.S. Court of Appeals for the First Circuit affirmed. Pet. App. 1a-24a. The appeals court held that Bartlett's design-defect claim was not impliedly preempted by the FDCA, relying on this Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009). *Id.* at 8a-11a. While conceding that "*Wyeth*'s holding was technically limited to failure-to-warn claims," it concluded that *Wyeth*'s "logic applies to design defect claims as well." *Id.* at 9a (citing 555 U.S. at 574). It interpreted the Court's 2011 *Mensing* decision as having merely "carved out an exception to *Wyeth*," applicable only to failure-to-warn claims asserted against manufacturers of generic drugs. *Id.*

The appeals court noted that Bartlett could have maintained a failure-to-warn claim against Merck had her druggist chosen to fill her prescription with Clinoril® rather than generic sulindac. The court concluded that that fact made it more likely that this Court would rule that Bartlett's design-defect claim was *not* preempted. Pet. App. 11a ("Bartlett having lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief."). The Court noted that Mutual was not forced to sell sulindac; "the decision to make the drug and market it in New Hampshire is wholly its own." *Id.* at 10a-11a.

The appeals court conceded that its decision was "in tension . . . with part of [*Mensing*'s] rationale" because the generic defendant in *Mensing* was similarly capable of "avoid[ing] defective warning lawsuits by not making the drug." Pet. App. 11a. It nonetheless

concluded that *Mensing* should be limited to failure-to-warn claims and that any new "exceptions" to *Wyeth*'s "general no-preemption rule" ought to come only from this Court. *Id.*

SUMMARY OF ARGUMENT

Congress has delegated to FDA the power to determine when a prescription drug is sufficiently safe and effective to warrant its distribution and sale in interstate commerce. 21 U.S.C. § 355. FDA approved the marketing of sulindac for several arthritis-related indications after determining that although sulindac poses significant dangers to some patients, its utility outweighed its risks. The judgment against Mutual conflicts with that determination. It is based on a state law determination that sulindac is a defective product because, as currently formulated, "the magnitude of the danger [created by sulindac's use] outweighs the utility of the product." Pet. App. 7a.

In light of that conflict, and the impossibility of Mutual continuing with its business in compliance with both federal and state law, Bartlett's design-defect claim is preempted by virtue of operation of the Supremacy Clause, U.S. Const., Art. VI, cl. 2. As explained by *Mensing*, "impossibility" is established by demonstrating that there is no action that a drug manufacturer could take that would bring its drug into compliance with both federal and state law. 131 S. Ct. at 2577-78. Both the appeals court and Bartlett concede that Mutual would have violated federal law had it sought to alter the composition of sulindac in order to address the design defect identified by the jury in this case. Indeed, *no* drug manufacturer is permitted under

federal law to make unilateral changes in the composition of an FDA-approved drug. Yet, the courts below determined that Mutual is in violation of New Hampshire law by marketing the FDA-approved version of sulindac.

"Impossibility" is not eliminated simply because the manufacturer could bring itself into compliance with both federal and state law by exiting the business entirely. As the appeals court recognized, Pet. App. 11a, that same option was available to the defendant in *Mensing*, yet the Court in that case did not deem the availability of a go-out-of-business option as sufficient to avoid preemption under an impossibility theory.

The design defect claim is also impliedly preempted because it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. As this Court has recognized, "Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background." *Weinberger v. Bentex Pharms. Inc.*, 412 U.S. 645, 654 (1973). In recognition of courts' lack of technical expertise, Congress delegated to FDA responsibility for undertaking the careful balancing process necessary to determine which prescription drugs (all of which are recognized to be highly dangerous to at least some patients) are sufficiently safe and effective to warrant their availability on a prescription basis. Allowing non-expert jurors to second-guess that balancing process, and to determine that some drugs are too dangerous to be marketed despite being approved by FDA, would undermine Congress's purposes and objectives.

For the reasons stated above, *all* design-defect claims against the manufacturers of prescription drugs are preempted by federal law. *Amici* agree with Mutual, however, that the rationale for preempting design-defect claims is particularly strong when, as here, the defendant is a generic drug manufacturer. Congress adopted the Hatch-Waxman Act in 1984 for the purpose of facilitating development of and marketing approval for low-cost, generic versions of FDA-approved drugs following expiration of the brand-name manufacturer's patent. Permitting state juries to second-guess the design of FDA-approved generic drugs would significantly undercut Congress's purposes and objectives in adopting Hatch-Waxman. In particular, generic manufacturers would not be able to offer their products at the low prices contemplated by Congress if they could not rely on FDA's prior determination that a drug formulation is safe and effective and instead would need to undertake their own extensive clinical trials to ascertain safety.

Finding preemption in this case will not, of course, leave patients who suffer injury after taking a prescription drug without legal recourse. If a patient can demonstrate that the drug was manufactured in a negligent manner and thus contained impurities, a state law tort suit would not be preempted. If FDA obtains new safety information and thereby determines that the drug should be removed from the market, it is at least arguable that a state-law tort suit against the manufacturer does not conflict with federal law and thus is not preempted. Moreover, the patient can sue the prescribing physician if the physician was negligent in writing the prescription. When, as here, the prescribing physician fails to read strong warnings

contained on the product label before prescribing the drug in question, he or she may be a prime candidate for liability.

ARGUMENT

I. BARTLETT'S DESIGN-DEFECT CLAIM IS PREEMPTED BECAUSE IT IS IMPOSSIBLE FOR MUTUAL TO BRING ITS DRUG INTO COMPLIANCE WITH BOTH FEDERAL AND STATE LAW

Mutual has cogently explained why this case is controlled by *Mensing* and why that decision requires a determination that Bartlett's design-defect claim is barred by a straight-forward application of conflict preemption principles.[2]

Amici write separately to focus on a different grounds for finding conflict preemption, one that applies without regard to the special Hatch-Waxman rules governing FDA approval of generic drugs. *See* Drug

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[2] As Mutual explained, "the Hatch-Waxman Act imposes 'an on-going duty of sameness' that precludes generic drugs from deviating in any material respects from their brand-name equivalents." Petitioners Br. at 1 (quoting *Mensing*, 131 S. Ct. at 2574-75). *Mensing* concluded that state law claims are impliedly preempted under the Constitution to the extent that they require generic manufacturers to violate Hatch-Waxman's "sameness" mandate as a precondition to engaging interstate commerce. Although *Mensing* arose in the context of a failure-to-warn claim, Mutual has demonstrated that *Mensing*'s sameness rationale applies equally to design-defect claims, particularly when (as here) those claims take into account the adequacy of the product's health and safety warnings. *Id.* at 29-45.

Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"). For more than half a century, Congress has delegated to FDA extremely broad authority to determine which drugs are sufficiently safe and effective to be distributed and sold in interstate commerce. Pursuant to the FDCA, FDA requires manufacturers to conduct extensive clinical testing—often at a cost of hundreds of millions of dollars—to demonstrate that the *design* of the drug (*i.e.*, its precise molecular structure) is safe when administered to humans for its intended use. *See, e.g.*, 21 U.S.C. § 355(b)(1)(A), (d). Manufacturers of an FDA-approved drug are not permitted to alter the drug's chemical composition; the altered product would be deemed an unapproved new drug whose distribution would constitute a felony. 21 U.S.C. § 331(d). Accordingly, those federal requirements would prevent manufacturers from altering a drug's design in response to a state's determination, as here, that the drug is defectively designed. When, as here, it is impossible for a drug manufacturer to simultaneously bring its drug product into compliance with both federal and state requirements, the Constitution requires that the latter be deemed preempted.

A. The Jury's Determination That the Risks of Sulindac Outweigh Its Benefits Conflicts with the Federal Government's Opposite Determination

It is well recognized throughout the medical community that prescription drugs can pose risks to health, even when prescribed by a treating physician,

and administered in accordance with FDA-approved labeling. Thus, when FDA approves a prescription drug for marketing, it does so not on the basis of findings that the drug poses *no* health risks but rather with the understanding that the health risks are manageable and are outweighed by the benefits to public health to be derived from making the drug available. 21 U.S.C. § 355(d).[3] FDA's approval of Merck's new drug application for Clinoril® in 1978 required FDA to undertake just such a risk/benefit analysis.

As the First Circuit recognized, many States will not second-guess FDA determinations that the risk/benefit balance favors approval of a manufacturer's marketing application. Pet. App. 5a ("[C]ourts 'traditionally have refused to review the reasonableness of the designs of prescription drugs.'") (quoting *Restatement (Third) of Torts: Product Liability* § 6, cmt. f, at 156 (1998)). Indeed, Bartlett concedes that many state courts "have taken the view that prescription drugs are, by definition, 'unavoidably unsafe'" and thus not subject to strict product liability based on claims that the drugs are defective. Respondent Opp. Cert. Br. at 12. Bartlett characterizes design-defect claims as "rare and exceedingly difficult to prove." *Id.*

The First Circuit concluded that New Hampshire is a State that permits juries to make an independent evaluation of the risk/benefit balance, and it affirmed the jury's verdict on that basis. Pet. App. 7a. Bartlett

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[3] Among the materials that FDA requires be included in new drug applications is "a discussion of why the benefits exceed the risks [of the drug] under the conditions stated in the labeling." 21 C.F.R. § 314.50(d)(5)(viii).

agrees with that characterization of New Hampshire law and the justification for the jury's verdict against Mutual:

> The question in New Hampshire is simply whether the product's risks outweigh its benefits; if so, the product is unreasonably dangerous, and the seller is subject to liability for injuries resulting from use of the product. . . . Applying those principles of New Hampshire law, the properly instructed jury in this case found that sulindac's risks outweighed its benefits, making it a defective product unreasonably dangerous to consumers.

Respondent Opp. Cert. Br. at 23.

The First Circuit recognized that the jury's verdict amounted to "second-guessing the FDA" with respect to the risk/benefit balance for sulindac. Pet. App. 10a. It nonetheless concluded that New Hampshire law was not preempted because Congress viewed FDA product approval as establishing a *minimum* design standard which States are permitted to exceed: "state law serves as a complementary form" of regulation of a drug's design. *Id.* at 9a.

The language and structure of the FDCA make plain that the appeals court erred in determining that Congress intended to permit juries applying state law to "second-guess[ ] the FDA" with respect to the design of prescription drugs. In particular, Congress provided that once FDA has approved the marketing of a prescription drug, it may seek to withdraw that approval only in accordance with elaborate rules set

forth in 21 U.S.C. § 355(e). FDA is required to provide "due notice" and an "opportunity for hearing" with respect to any such withdrawal. *Id.* Section 355(e) sets forth a limited number of grounds that would justify a decision to pull a drug from the market. The listed grounds have an important element in common: they all require FDA to be acting on the basis of information that became available *after* the drug was initially approved for marketing. In other words, Congress did not permit FDA officials to second-guess the product-approval decisions of their predecessors based solely on a difference of opinion regarding the risk/benefit evidence submitted to FDA in the initial product-approval application.

Congress cannot plausibly be understood to have intended to limit *FDA*'s power to revoke marketing authority for a prescription drug, yet at the same time to have granted *a State* unlimited power to declare FDA-approved drugs to be defectively designed and thereby to bar their distribution within the State.

Nor is there reason to conclude that Congress intended to grant a State the more limited authority to bar the distribution of drugs that fail (in the State's view) to meet the product design standards established by FDA, or that arguably should have had their marketing approval withdrawn under § 355(e). This Court has rejected efforts by anyone other than the United States to enforce federal drug laws. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4, 352 (2001) (citing 21 U.S.C. § 337(a)). *Buckman* held that state-law tort claims based on allegations that a drug manufacturer obtained FDA marketing authority by supplying false information to FDA were impliedly

preempted because they conflicted with FDA's own enforcement responsibilities. *Id.* at 348. The Court explained that FDA uses its powers to punish and deter fraud "to achieve a somewhat delicate balance of statutory objectives," and that to allow others to play a role in enforcing those powers might upset that balance. *Id.* Similarly, granting States a role in determining whether a drug's risk/benefit balance is sufficiently unfavorable to justify a product ban would undercut the risk/benefit balancing role that Congress assigned to FDA.

B. Impossibility Preemption Is Not Eliminated Simply Because Mutual Could Bring Itself Into Compliance with Both Federal and State Law by Ceasing Production

The Supremacy Clause requires preemption of state laws whenever they conflict with federal law. *Arizona v. United States*, 132 S. Ct. 2492, 2501 (2012). "This includes cases where compliance with both federal and state regulations is a physical impossibility and those instances where the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (citations omitted).

The Court deems compliance with both federal and state laws to be a "physical impossibility" when "[i]t is not lawful under federal law" for drug manufacturers "to do what state law required of them." *Mensing*, 131 S. Ct. at 2577. That definition fits this case precisely. The jury concluded that, under New Hampshire law, sulindac is defectively designed and thus may not

continue to be marketed with its current formulation. Yet, as noted above, federal law prohibits drug manufacturers from altering the formulation of FDA-approved drugs. Thus, it is a "physical impossibility" for Mutual to operate its business in a manner that satisfies both federal and state law.

The First Circuit recognized that conundrum but nonetheless deemed impossibility preemption inapplicable because Mutual "certainly can choose not to make the drug at all," thereby bringing itself into compliance with both federal and state law. Pet. App. 10a. That conclusion is inconsistent with the Court's holding in *Mensing*. The defendant in that case had the identical ability to bring itself into compliance with both federal and state law by ceasing production of metoclopramide, the drug whose labeling was at issue. The Court nonetheless had no difficulty in concluding that the state regulation at issue (which prohibited distribution of metoclopramide unless the manufacturer included a stronger health warning on the product label) was barred under impossibility preemption principles. 131 S. Ct. at 2577-79.

Indeed, the case for application of impossibility preemption is even stronger here than it was in *Mensing*. In the latter case, state law provided the generic drug manufacturer with an option that offered it at least some hope that it could eventually resume the marketing of metoclopramide. It could have asked FDA and the brand-name drug company to sufficiently strengthen warnings on metoclopramide's labeling to satisfy state-law requirements; and those parties possessed statutory authority to grant the request. *Id.* at 2578. In contrast, both the First Circuit and Bartlett

recognized that a similar request in this case could never provide Mutual with a solution to the impossibility conundrum, not even in the long term. Pet. App. 10a ("Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)."). Thus, the *only* option available to Mutual in the face of conflicting regulations is to cease production altogether.[4]

The "impossibility" conundrum facing manufacturers is heightened by the fact that, if the decision below is affirmed, they are likely to face multiple product design standards from different States. Indeed, it is quite plausible that they will face

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[4] Similarly unavailing is Bartlett's effort to distinguish *Mensing* by arguing that in that case the state law "required the manufacturers to attach a safer label to their generic metoclopramide," not to withdraw its product from the market. Respondent Opp. Cert. Br. 26. Bartlett asserts:

> When, as in [*Mensing*], a holding under state law would obligate a party to take an action (such as changing the label for its product) that federal law prohibits, that claim is preempted, even if the party could avoid liability by removing its product from the market. Here, by contrast, the holding under New Hampshire law did not require petitioner to perform any act that federal law prohibits it from doing independently.

Id. The distinction Bartlett seeks to draw between this case and *Mensing* is mere word-play. As the First Circuit recognized, the jury verdict in *Mensing* provided the drug company defendant with the same "out" that New Hampshire provided to Mutual: withdrawal from the market. Pet. App. 10a. The duty imposed by the jury verdict in *Mensing* was the duty to cease marketing metoclopramide in the absence of labeling providing health warnings that were not authorized by FDA.

conflicting design standards from two juries within a single State. Such multiple conflicting standards would all but guarantee that a manufacturer would respond by withdrawing from the market on a nationwide basis, thereby depriving patients of medical products that FDA has deemed beneficial to public health. In the context of medical devices, this Court concluded that Congress barred state-law regulation of the design of Class III medical devices at least in part because it feared that conflicting regulation of product design would stifle development of new and useful medical products. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 326 (2008).

In light of the clear "impossibility" conflict between the jury's verdict and FDA's approval of sulindac's current design, the Court should not strain to save the jury verdict from preemption. As the *Mensing* plurality observed, the Supremacy Clause was drafted in the form of a *non obstante* provision and therefore "suggests that federal law should be understood to impliedly repeal conflicting state law." *Mensing*, 131 S. Ct. at 2580 (plurality opinion). Accordingly, "courts should not strain to find ways to reconcile federal law with seemingly conflicting state law." *Id.* Under the facts of this case, it would require considerable straining for the Court to conclude that Congress intended to permit States to prevent the marketing of a prescription drug despite FDA's considered judgment that the drug's benefits outweigh its risks.

The appeals court's reliance on *Wyeth* was misplaced; that decision is clearly distinguishable. *Wyeth* found that failure-to-warn claims against brand-name drug companies were not subject to impossibility

preemption because federal law permitted the companies to unilaterally strengthen their labeling for the purpose of improving drug safety pursuant to FDA's "changes being effected" regulation, 21 C.F.R. § 314.70(c)(6)(iii)(A), (C). *Wyeth*, 555 U.S. at 568. There is no analogous federal regulation that permits manufacturers to make unilateral changes in a drug's design.

Indeed, Justice Thomas's concurring opinion in *Wyeth* makes clear the limited nature of that decision. Justice Thomas deemed impossibility preemption to be inapplicable in *Wyeth* in part because federal drug laws "do not give drug manufacturers an unconditional right to market their federally approved drug at all times *with the precise label initially approved by the FDA*," but rather require brand-name manufacturers to add new warnings "as soon as there is reasonable evidence of an association of a serious hazard with a drug." *Id.* at 592 (Thomas, J., concurring in the judgment) (emphasis added) (quoting 21 C.F.R. § 201.80(e)). In contrast, federal drug laws *do* provide manufacturers with a right to continue marketing their FDA-approved products as designed, until such time as FDA complies with statutory requirements that constrain its power to withdraw marketing authority. *See, e.g.*, 21 U.S.C. § 355(e).

Finally, a decision in Mutual's favor will not produce the anomalous result that the *Mensing* dissenters found so troubling. When *Mensing* and *Wyeth* are considered together, the result is that an injured patient can maintain a failure-to-warn claim against a brand-name drug company, but he loses that right if his pharmacy elects to fill his prescription by

substituting a generic drug for the brand-name drug prescribed by the doctor. While *Mensing* explained that distinction by pointing to federal drug law's disparate treatment of brand-name and generic manufacturers (the former are entitled to make unilateral label changes while the latter are not), the Court recognized that "from the perspective of [the plaintiffs], finding preemption here but not in *Wyeth* makes little sense." *Mensing*, 131 S. Ct. at 2581.

No similar distinction exists between brand-name and generic manufacturers with respect to product design. Neither category of manufacturer is entitled under federal drug law to make unilateral changes in product design. "Impossibility preemption" applies to a state law design-defect claim, regardless whether the defendant is a brand-name or a generic manufacturer. Because the "impossibility preemption" rule espoused here applies in a predictable and uniform manner, there is no reason to question the likelihood that Congress would have intended to adopt such a rule.

II. BARTLETT'S CLAIM IS ALSO PREEMPTED BECAUSE IT OBSTRUCTS ACCOMPLISHMENT OF CONGRESS'S PURPOSES

Conflict preemption doctrine also requires that a challenged state law give way when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 132 S. Ct. at 2501. The reasons previously articulated for finding "impossibility" preemption also suffice to find that the jury's verdict is subject to "purposes and objectives" preemption.

As this Court has recognized, "Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background." *Weinberger v. Bentex Pharms. Inc.*, 412 U.S. 645, 654 (1973). In recognition of courts' lack of technical expertise, Congress delegated to FDA responsibility for undertaking the careful balancing process necessary to determine which prescription drugs (all of which are recognized to be highly dangerous to at least some patients) are sufficiently safe and effective to warrant their availability on a prescription basis. Allowing non-expert jurors to second-guess that balancing process, and to determine that some drugs are too dangerous to be marketed despite being approved by FDA, would undermine Congress's purposes and objectives.[5]

"Evaluation of conflicting reports as to the

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[5] Bartlett contends that Mutual has waived its right to assert "purposes and objectives" preemption because it allegedly failed to articulate that argument in its certiorari petition. Respondent Opp. Cert. Br. at 21, 28 n.22. That contention is without merit. The Court granted certiorari to consider the issue of whether conflict preemption doctrine bars Bartlett's design-defect claim. Once review is granted to consider an issue, the Court has never limited the parties to the specific arguments on that issue that were raised or considered previously. *See Lebron v. Nat'l Railroad Passenger Corp.*, 513 U.S. 374, 379 (1995) ("Our traditional rule is that 'once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they raised below.'") (quoting *Yee v. Escondido*, 503 U.S. 519, 534 (1992)). Accordingly, with respect to the conflict preemption issue, Mutual is entitled to argue both "impossibility" preemption and "purposes and objectives" preemption without regard to the extent to which those arguments have previously been raised.

reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background." *Id.* Thus, federal courts of appeals have repeatedly held that whether a drug is safe and effective is squarely within the primary scope of FDA's regulatory authority.[6]

FDA's requirements as to drug safety and labeling are imposed through a regulatory scheme that closely parallels the regulatory scheme for Class III medical devices that the Court found to have a preemptive effect in *Riegel*. And as with Class III medical devices, FDA's determinations as to which

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[6] *See, e.g.*, *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 257 (3d Cir. 2008) ("FDA is charged with promoting the public health" by, *inter alia*, "ensuring that drugs are safe and effective") (internal quotations and citation omitted); *Zeneca, Inc. v. Shalala*, 213 F.3d 161, 170 (4th Cir. 2000) ("FDA's 'judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us.'") (quoting *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995), and *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995)); *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) (same); *Rutherford v. United* States, 806 F.2d 1455, 1461 (10th Cir. 1986) ("[T]he intent behind the [FDCA] was to give the agency primary jurisdiction to determine evidentiary matters concerning drugs about which it has a special expertise"); *United States v. Undetermined Quantities of Various Articles of Drug Equidantin Nitrofurantion Suspension*, 675 F.2d 994, 1000 (8th Cir. 1982) ("A district court is not empowered to evaluate the actual safety and effectiveness of a drug product. That determination is committed to the FDA due to its superior access to technical expertise."); *Premo Pharm. Labs. Inc. v. United States*, 629 F.2d 795, 803 (2d Cir. 1980) (question whether a drug is safe and effective "is to be determined by the FDA which, as distinguished from a court, possesses superior expertise, usually of a complex scientific nature, for resolving the issue").

drugs should be approved reflects "a cost-benefit analysis" in which FDA balances how many "lives will be saved" by the drug against the "risk of harm." *Riegel*, 552 U.S. at 325. *Riegel* noted that, by way of contrast, juries considering state-law tort claims engage in no such cost-benefit analysis. A jury "sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court." *Id.*

The need for FDA to pursue this balanced approach was recognized by Congress in its amendment of the FDCA in 1962. As set forth in the Senate Report accompanying the 1962 Amendments, the new drug application approval procedures were designed to "strike [ ] a balance between the need for government control to assure that new drugs are not placed on the market until they have passed the relevant tests and the need to insure that government control does not become so rigid that the flow of new drugs to the market, and the incentive to undergo the expense involved in preparing them for market, become stifled." Drug Amendments of 1962, S. Rep. No. 87-1744 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 2884.

In enacting the 1997 FDA Modernization Act, Congress reaffirmed this basic principle, declaring "a clearly defined, balanced mission for the FDA" which reflects both the federal objectives of "protecting the public health by ensuring that the products [FDA] regulates meet the appropriate FDA regulatory standards" and of "taking appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability." Food and Drug Administration Modernization Act of

1997, S. Rep. No. 105-43 (1997), as printed in 1997 WL 394244, at *2-*4; *see also id.* at *10 (mission statement added to FDCA because "[c]lear statutory guidance is needed to assist the Agency to find this delicate balance"). Congress instructed: "the agency should be guided by the principle that expeditious approval of useful and safe new products enhances the health of the American people. Approving such products can be as important as preventing the marketing of harmful or ineffective products." *Id.* at *8, *15. This balanced mission statement is set forth in FDA regulation, 21 U.S.C. §§ 393(b)(1) & (b)(2)(B) (2008),[7] and is reflected in the Court's discussion in *Buckman* of FDA's "often competing" regulatory objectives. *Buckman*, 531 U.S. at 348, 349-50 (2001).

Permitting individual juries to second-guess FDA's product approval decisions is inconsistent with Congress's intent that FDA should adopt a "balanced" approach when making those decisions. By prohibiting the sale and distribution of a prescription drug whose benefits, FDA has determined, outweigh its risks, the jury verdict in this case stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

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[7] FDA is charged under these regulations with "promot[ing] the public health by promptly and efficiently reviewing [drug manufacturers'] clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and "protecting the public health by ensuring that...drugs are safe and effective." 21 U.S.C. §§ 393 (b)(1) & (b)(2)(B) (2008).

III. FINDING PREEMPTION HERE WILL NOT LEAVE PATIENTS WITHOUT LEGAL RECOURSE

The First Circuit based its decision in part on a desire to be fair to tort plaintiffs who allege that a generic drug caused them injury: "Bartlett having lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief." Pet. App. 11a. But this Court has never based its product liability preemption decisions on a "sporting chance" rationale, whereby every injured plaintiff ought to have at least one shot at receiving compensation for his damages. Rather, the Court looks solely to congressional intent in determining whether state regulations are preempted. *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978) ("The purpose of Congress is the ultimate touchstone" of preemption analysis).

At least as importantly, a decision favoring Mutual in this case will not leave patients without legal recourse for their injuries. The appeals court referred to "the perennial trio of products liability claims: design defect, failure to warn, and manufacturing defect." Pet. App. 3a. Bartlett asserted all three of those claims against Mutual. *Id.* The failure-to-warn and manufacturing-defect claims did not survive to trial—not because the trial court deemed them preempted but because they were found deficient as a matter of New Hampshire law. *Wyeth* ensures that injured plaintiffs can continue to assert failure-to-warn claims against brand-name drug companies, and *amici* are unaware of *any* appellate court that has held that a

manufacturing-defect claim is preempted by federal law.[8]

Moreover, an injured patient can sue the prescribing physician if the physician was negligent in writing the prescription. When, as here, the prescribing physician fails to read strong warnings contained on the product label before prescribing the drug in question, he or she may be a prime candidate for liability. *See Wyeth*, 555 U.S. at 619-21 (Alito, J., dissenting).

Finally, if FDA obtains new safety information and thereby determines that the drug is unreasonably unsafe and should be removed from the market, it is at least arguable that a state-law design-defect suit against the manufacturer does not conflict with federal law and thus is not preempted. Under those circumstances, a tort suit might be viewed as serving to supplement and facilitate the federal enforcement scheme. Thus, in *Buckman*, Justices Stevens and Thomas opined that the preempted fraud-on-the-FDA claim "would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the [product-approval] process and had then taken the necessary steps to remove the

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[8] Moreover, a finding that design-defect claims are preempted will affect only a small fraction of legal claims filed by those claiming injury as a result of using a prescription drug. Indeed, Bartlett concedes that many state courts "have taken the view that prescription drugs are, by definition, 'unavoidably unsafe'" and thus not subject to strict product liability based on claims that the drugs are defective. Respondent Opp. Cert. Br. at 12. Bartlett characterizes design-defect claims as "rare and exceedingly difficult to prove." *Id.*

harm causing product from the market. . . . In such a case, a plaintiff would be able to establish causation without second-guessing the FDA's decision-making." *Buckman*, 531 U.S. at 355 (Stevens, J., concurring in the judgment).

There is no cause for the Court to speculate on these counter-factual possibilities. FDA has not determined that sulindac is unreasonably unsafe. The drug continues to be marketed by Mutual and other drug manufacturers, and there is no evidence that Mutual obtained marketing approval by providing false information to FDA. It suffices to observe that a ruling in favor of Mutual will not (as some drug industry critics have charged) leave injured patients without any legal recourse against those that have wronged them.

IV. THE RATIONALE FOR PREEMPTING DESIGN-DEFECT CLAIMS IS PARTICULARLY STRONG WHEN THE DEFENDANT IS A GENERIC DRUG MANUFACTURER

For the reasons stated above, *all* design-defect claims against the manufacturers of prescription drugs are preempted by federal law. *Amici* agree with Mutual, however, that the rationale for preempting design-defect claims is particularly strong when, as here, the defendant is a generic drug manufacturer. Congress adopted the Hatch-Waxman Act in 1984 for the purpose of facilitating development of and marketing approval for low-cost, generic versions of FDA-approved drugs following expiration of the brand-name manufacturer's patent. Permitting state juries to second-guess the design of FDA-approved generic drugs

would significantly undercut Congress's purposes and objectives in adopting Hatch-Waxman.

Congress adopted the Hatch-Waxman Act "to make available more low cost generic drugs." H.R. Rep. 98-857, pt. 1, at 14. Under the law, generic drugs can gain FDA approval "simply by showing equivalence to" a brand name drug that has already been approved by FDA. *Mensing*, 131 S. Ct. at 2574. Indeed, FDA is not permitted to require one of these "abbreviated" new drug applications (ANDAs) to "contain information in addition to" the very limited categories of information specified in Hatch-Waxman. 21 U.S.C. § 355(j)(2)(A). As the Court has explained, Hatch-Waxman "allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." *Mensing*, 131 S. Ct. at 2574.

Permitting design-defect tort claims to be filed against generic manufacturers would undercut Congress's desire that generic drugs serve as a low-cost alternative to brand-name drugs. Faced with the prospect of multi-million dollar tort judgments, generic manufacturers would no longer be willing to accept at face value FDA's determination that a drug's benefits outweigh its safety risks and thus that the drug is not unreasonably unsafe. Instead, prudent generic manufacturers would begin undertaking extensive clinical trials of their own to satisfy themselves that the drug design is a safe one and thus that marketing the drug would not expose the company to potentially ruinous liability. Because the cost of such studies would invariably be incorporated into the prices charged by generic manufacturers, generic drugs would no longer

be available at the low prices contemplated by Congress when it adopted the Hatch-Waxman Act.

The legislative history is replete with statements indicating that Congress intended that generic drugs would, in fact, be produced at minimum cost and thus be made available for sale at very low prices. *See, e.g.*, H.R. Rep. 98-857, pt. 1, at 17 ("The availability of generic versions of pioneer drugs approved after 1962 would save American consumers $920 million over the next 12 years."); *id.* at 18 ("Enactment of the legislation, however, will result in significant cost savings to the Federal government. Unlike the costs of H.R. 3605, *these savings are certain*. The Federal government spent about $2.4 billion for drugs in 1983. Many of these drugs will be available as low cost generic after enactment of H.R. 3605.") (emphasis added). Congress could be "certain" that the cost structure for generic drugs would remain low only if generic manufacturers' pricing would not have to factor in costs associated with design-defect litigation and could reasonably rely on FDA findings that FDA-approved drugs are not unreasonably dangerous.

Moreover, Congress was adamant that generic manufacturers should *not* undertake their own clinical studies, not only because they were deemed "unnecessary and wasteful" but also because Congress considered them "unethical":

> The only difference between a NDA and an ANDA is that the generic manufacturer is not required to conduct human clinical trials. FDA considers such retesting to be unnecessary and wasteful because the drug has already been

> determined to be safe and effective. Moreover, such retesting is unethical because it requires that some sick patients take placebos and be denied treatment known to be effective.

Id. at 16. A Congress that deemed additional safety testing of FDA-approved drugs to be so unnecessary as to be "wasteful" and "unethical" cannot reasonably be understood to have simultaneously contemplated that state law would serve as a "complementary form of drug regulation," Pet. App. 9a, and that juries applying state law would be permitted to determine that FDA-approved drugs were unreasonably dangerous.

CONCLUSION

Amici curiae request that the Court reverse the decision of the court of appeals.

Respectfully submitted,

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